MASTER OF PHILOSOPHY

A study exploring quality of life and unmet needs of patients with heart failure in a General Practice population

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A study exploring quality of life and unmet needs of patients with heart failure in a General Practice population

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Dedication

I would like to dedicate this thesis to the memory of my beloved grandparents Tommy and Sheila who were always so proud of my achievements and who passed away during the course of this work.

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To mum and dad without whose love, encouragement and sacrifice my achievements would not have been possible.

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Abbreviations

ACE	Angiotension receptor blocker
CHF	Congestive heart failure
CHFQ	Chronic heart failure questionnaire
CIBIS	Cardiac insufficiency bisoprolol study
COOP	Dartmouth Primary Care Co-operative Information Project
ECG	Electrocardiogram
ECHOES	Echocardiographic heart of England screening study
GMS	General medical services
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HUI	Health Utilities Index
KCCQ	Kansas City Cardiomyopathy Questionnaire
LVD-36	Left Ventricular Dysfunction questionnaire
LVSD	Left ventricular systolic dysfunction
MLwHF	Minnesota Living with Heart Failure Questionnaire
MCS	Mental component scale
NHP	Nottingham Health Profile
NICE	National Institute of Clinical Excellence
NI MDM	Northern Ireland Multiple Deprivation Measure
NYHA	New York Heart Association
PCS	Physical component scale

PHQ-9	Patient Health Questionnaire
QLQ-SHF	Quality of Life Questionnaire for severe Heart Failure
QOF	Quality and Outcomes Framework
QOL	Quality of Life
QWB	Quality of Well-being scale
SD	Standard deviation
SF-12	Short Form 12
SF-36	Short Form 36
SIP	Sickness Impact Profile
SPSS	Statistical package for social sciences
SOA	Super output area
SOLVD	Study of Left Ventricular Dysfunction
WHO	World Health Organisation

Chapter 1 - Heart Failure in Primary Care

Introduction

"Congestive heart failure (CHF), a clinical syndrome due to heart disease, characterised by breathlessness and abnormal sodium and water retention, often resulting in oedema. The congestion may occur in the lungs or peripheral circulation or both, depending on whether the heart failure is right-sided or generalised."
(Saunders 2000)

Congestive heart failure is the end stage of functional and structural diseases of the heart. The most common cause of heart failure in the United Kingdom is coronary heart disease which accounts for approximately 36% of cases.(Cowie et al. 1999) Other primary aetiologies include hypertension, valvular heart disease, arrhythmias in particular atrial fibrillation, and heart muscle abnormalities such as cardiomyopathies.

The clinical condition heart failure has been recognised for many centuries. It was described by many of the ancient civilisations and early treatments included the use of foxglove, blood-letting and leeches. The work of William Harvey on the circulation in the early 1600's increased understanding of the pathophysiology of heart failure. Important landmarks in the natural history of

this condition include the introduction of thiazide diuretics in 1958 and the CONSENSUS trial which showed improved survival in heart failure patients with ACE inhibitors in 1987. (Davis, Hobbs & Lip 2000) More recent advances in treatment such as implantable cardiac defibrillators and surgical interventions have improved survival but despite an improved understanding of heart failure and its treatments, the disease remains incurable. While survival has increased dramatically in recent years (Levy et al. 2002) progressive decline in health and ultimately death are inevitable.

Pathophysiology of heart failure

The heart and peripheral blood vessels adapt in heart failure in order to maintain cardiac output and peripheral tissue perfusion. This compensatory process allows good levels of function when heart failure is mild, however as the disease progresses these mechanisms may become inadequate and clinical symptoms develop.

There are many different clinical syndromes of heart failure. There are usually classified according to chronicity or the site of the heart affected.

Acute heart failure describes the sudden onset of cardiac failure which usually occurs in the setting of myocardial infarction when there is loss of ventricular muscle function. If the underlying cause is treated the heart function may return but often these patients go on to develop chronic heart failure.

The term chronic heart failure refers to any clinical heart failure syndrome which is not acute. Chronic heart failure may be further categorised into left heart failure, right heart failure, systolic heart failure and diastolic heart failure. Other less common descriptive terms include high output, low output, dilated, non-dilated, ischaemic cardiomyopathy and hypertensive cardiomyopathy.

Left heart failure is a failure of adequate output by the left ventricle usually as a result of ischemic heart disease, hypertension, acquired mitral or aortic valvular

regurgitation, aortic stenosis, most forms of cardiomyopathy, and congenital heart disorders. The symptoms of left heart failure are predominantly dyspnoea, orthopnoea, paroxysmal nocturnal dyspnoea and fatigue.

In contrast right heart failure is a failure of normal functioning of the right ventricle which usually occurs in association with left heart failure, pulmonary or tricuspid valve disease or lung disorders such as chronic lung disease or pulmonary hypertension. As with left heart failure, fatigue is a feature of right heart failure but in addition, patients with this condition also complain of breathlessness, anorexia and nausea due to fluid accumulation and resulting distention of the systemic veins.

In systolic heart failure or systolic ventricular dysfunction, the ventricle contracts poorly and empties inadequately leading to a decreased ejection fraction (Figure 1). Systolic heart failure is most commonly due to myocardial infarction, myocarditis, and dilated cardiomyopathy. Systolic heart failure may affect primarily the left ventricle or the right ventricle.

Diastolic heart failure or diastolic ventricular dysfunction is caused by impaired ventricular relaxation leading to impairment of diastolic ventricular filling and therefore reduced cardiac output. This condition is particularly common in the elderly as resistance to filling increases with age, probably due to myocyte loss and increased collagen deposition in the myocardium. Diastolic heart failure also

predominates in hypertrophic cardiomyopathy, hypertension, aortic stenosis, coronary artery disease and rarely amyloid infiltration of the myocardium.

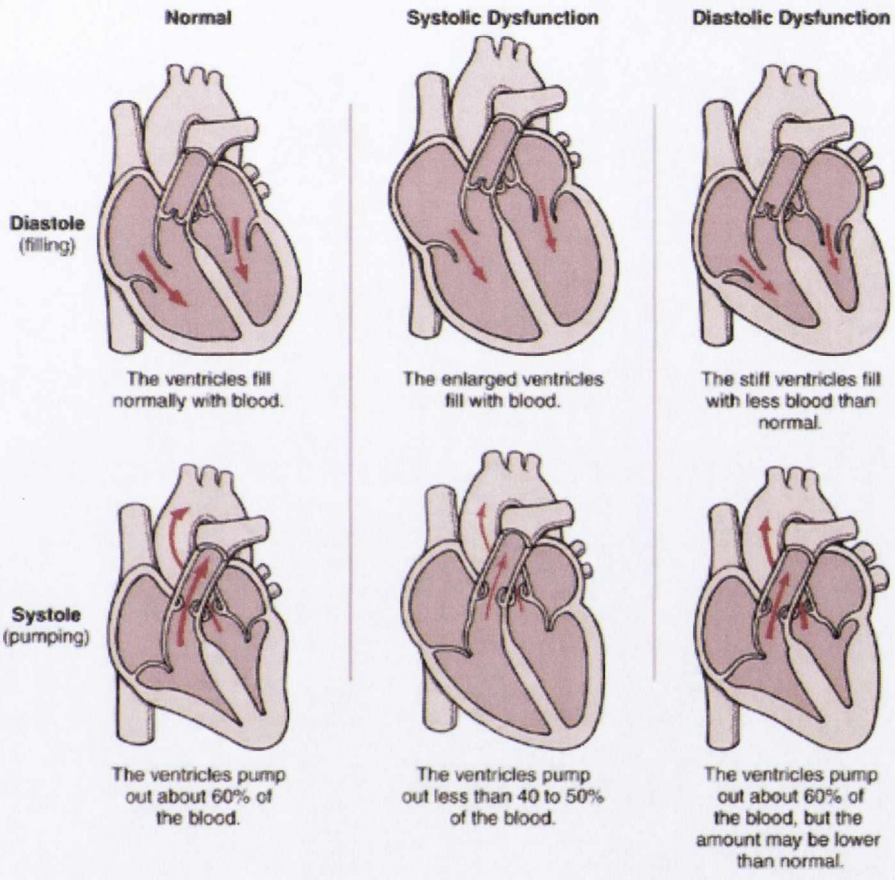

Figure 1

Image from www.med.uc.edu, downloaded 13th July 2009

The distinctions of left, right, systolic and diastolic heart failure indicate the site of pathology leading to heart failure and can be useful for investigation and management. However as the heart is an integrated pump it is rare for any part to fail in isolation. Therefore in clinical practice it is more common to see patients with elements of both left and right, and diastolic and systolic heart failure. The term congestive heart failure is therefore used in clinical settings to describe the clinical syndrome which may present with a mixture of symptoms and signs.

Epidemiology of heart failure in the United Kingdom

Historically there have been difficulties in obtaining accurate data on the epidemiology of heart failure due to a lack of agreement on a definition for heart failure. Although heart failure is a clinical diagnosis many studies have used left ventricular ejection fractions obtained from echocardiograms to define levels of dysfunction. As there is no agreed cut-off value for an ejection fraction which indicates a diagnosis of heart failure each study has used different values, leading to conflicting data.(Davis, Hobbs & Lip 2000)

The Framingham heart study, based in the United States of America, is a unique longitudinal study which commenced in 1948 and spans two generations. The Framingham heart study assessed 5209 patients every 2 years from 1948 to try and determine the incidence and prevalence of heart failure. Incidence rates from the Framingham data show an annual rate of 0.14% for women and 0.23% for men when adjusted for age. The Framingham study also noted that the prevalence and incidence of heart failure increased dramatically with age and that the incidence is higher in men than in women.(Ho et al. 1993b)

The Framingham study data have been followed by more recent studies including the Hillingdon study which was based in general practice. In the Hillingdon heart study new cases of heart failure, presenting in the period April 1995 to December 1996, were identified from a population of 151,000 served by 82 general practices in Hillingdon, London UK. They reported incidence rates

from 0.2 per 1000 in those aged 35-44 years increasing to 11.6 per 1000 in those over 85 years and they identified a median age of presentation of 76 years. Figure 2 shows how they found the incidence to increase with age and amongst men more than women. The most common underlying aetiological conditions were coronary heart disease, hypertension, valvular disease and atrial fibrillation.(Cowie et al. 1999)

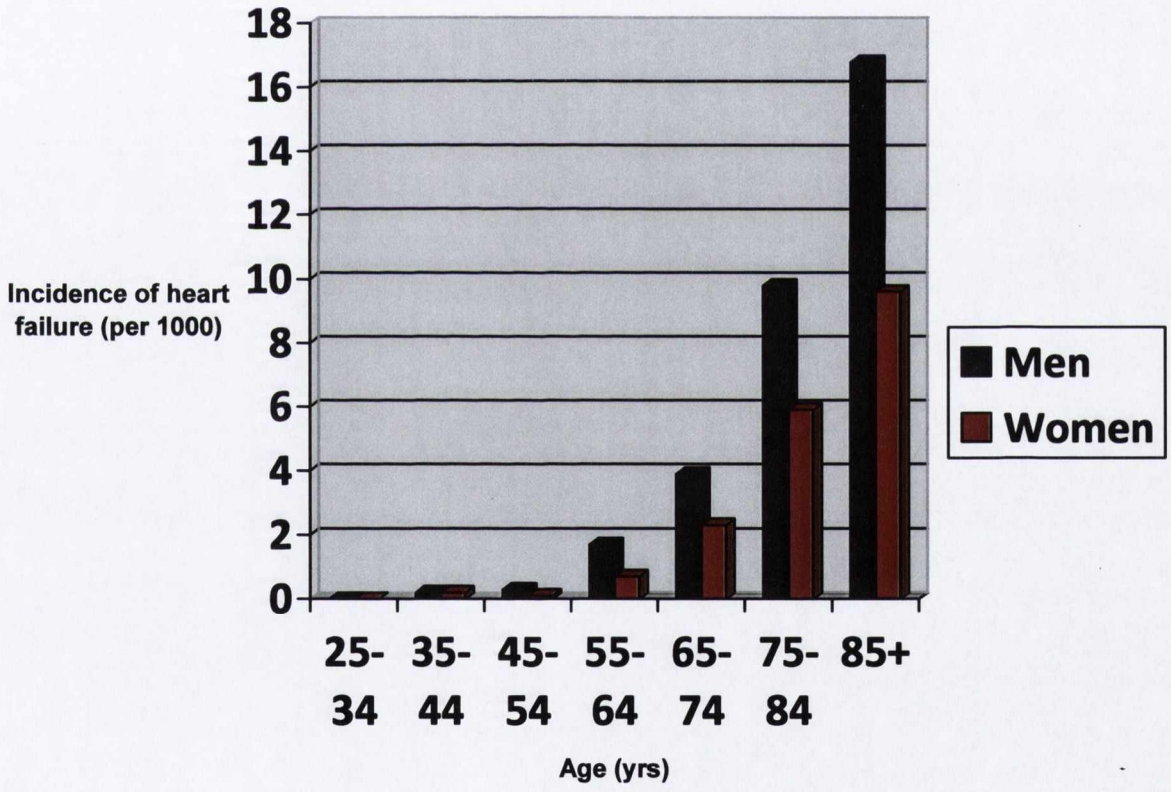

Figure 2

Incidence of heart failure per 1000 in adults at different age groups adapted from the Hillingdon Heart Study (Cowie et al. 1999)

Information from these studies and the increasing heart failure hospital admission rates in the United Kingdom (British Heart Foundation 2004) suggest that the incidence of heart failure is increasing. The incidence of heart failure is directly associated with increasing age. (Cowie et al. 1999) As life expectancy in the United Kingdom is increasing the incidence of heart failure will increase due to the rising older population. Ongoing advances in medical and surgical treatments have also contributed to the increase in heart failure incidence. These advances lead to higher survival rates from cardiac conditions such as myocardial infarction. Patients who survive cardiac events will often have impairment in heart function and develop chronic heart failure. Another factor which may contribute to increasing numbers of patients with heart failure is the improvement in mortality rates due to standardisation of care based on evidence based guidelines in primary and secondary care, for example the Department of Health National Service Framework for coronary heart disease (Department of Health 2000) and the NICE guidance for management of chronic heart failure (National Institute for Health and Clinical Excellence 2003). There is evidence that the incidence of heart failure patients in general practice is increasing.(Ellis, Gnani & Majeed 2001) With the rising elderly population the number of patients in the community with heart failure is set to continue to increase with significant implications for the provision of community based care.

Heart failure accounts for over 5% of medical admissions to hospital in the United Kingdom. The total direct medical cost of CHF in the UK is currently

estimated in excess of £625 million with hospital inpatient care accounting for approximately 60% of this total.(British Heart Foundation 2007) The costs accrued in the primary sector are also significant with an estimated 7.6 million general practice consultations for heart failure in the United Kingdom in 2000. The approximate cost of this condition to general practice is approximately £104 million per year. (British Heart Foundation 2007) Data from the Quality and Outcomes Framework would indicate that in 2007 there were approximately 15,000 patients with heart failure in Northern Ireland. (Department of Health, Social Services and Public Safety, Northern Ireland 2007) However the true number of patients living with the condition is likely to be much higher due to underreporting.

A diagnosis of heart failure can be suspected from clinical symptoms and signs but should always be confirmed using an objective measure of ventricular structure and function. The National Service Framework for coronary heart disease supports the use of an objective measure for accurate diagnosis when heart failure is suspected in primary care. (Department of Health 2000) Prior to this publication a diagnosis was often made by general practitioners on the basis of clinical features alone. With the introduction of the new General Medical Services contract in 2004 came the Quality and Outcomes framework (QOF). The QOF was intended to improve the quality of general practice care and reward GPs for implementing good evidence based practice in their surgeries. GP's were rewarded financially for meeting targets in various clinical and

organisational domains. The clinical domains included targets in chronic disease areas such as heart failure.

A total of 1000 points are available to GPs for meeting the requirements set out by QOF. Currently, 20 of these points are allocated for heart failure targets. To obtain these points practices are expected to meet the criteria listed below:

- Produce a register of heart failure patients
- The information should include the percentage of patients with a diagnosis of heart failure which has been confirmed by an echocardiogram or by specialist assessment and this should be between 40 and 90%. Those who do not have a confirmed diagnosis should have the reason for exemption reported. Referral for Echocardiogram or specialist to be made within 12 months of diagnosis or within 3 months before diagnosis entered for diagnoses made after 1st April 2006
- Record the percentage of patients with a current diagnosis of heart failure due to LVSD (left ventricular systolic dysfunction) who are currently treated with an ACE inhibitor or Angiotensin Receptor Blocker, who can tolerate therapy and for whom there is no contra-indication also needs to be listed and should be between 40 and 80%.

The introduction of QOF has not only improved the treatment of patients though standardisation of care and evidence based practice, but also made GP records of patients with chronic disease more accurate and searchable. Previously in research of heart failure in general practice the selection and therefore recruitment of patients has been difficult. Patients were identified on the basis of disease codes for heart failure and also on the basis of drug therapies used to treat heart failure. As a result patients who did not have a confirmed diagnosis of heart failure or were on drug treatments for other conditions may have been identified from searches. However, with a need for GPs to review patients on their heart failure registers on a yearly basis, to meet QOF targets, more accurate identification of patients is now possible.

Symptoms of heart failure

In left sided heart failure, the most common symptoms are dyspnoea, and fatigue. Breathlessness can present in various ways, depending on the severity of heart failure. In milder cases of heart failure patients may be completely asymptomatic or may complain of exertional dyspnoea, which is dyspnoea which occurs during exertion and is relieved by rest. The degree of activity which induces exertional dyspnoea will vary depending on the level of left ventricular failure. Exertional dyspnoea may be absent in patients with very severe failure if they have low activity levels or are sedentary.

As the heart failure progresses, dyspnoea can occur during rest and at night resulting in orthopnoea and paroxysmal nocturnal dyspnoea. Orthopnoea describes breathlessness occurring immediately or soon after lying flat and relieved promptly by sitting up while paroxysmal nocturnal dyspnoea (PND) is breathlessness which awakens patients from sleep and is relieved only after sitting up.

Non-specific symptoms such as fatigue and weakness are very common in heart failure patients. These generally develop due to poor perfusion of the skeletal muscles resulting in structural and metabolic changes. Although these features are generally reported in more severe heart failure, intermittent fatigue and weakness are also common in earlier stages. Other non-specific symptoms

include cool peripheries, dizziness, nocturia, and weight loss. Significant weight loss is a poor prognostic sign and is associated with high mortality.

Reduced cardiac output resulting in reduced cerebral blood flow and hypoxaemia may affect cerebral function. In studies assessing the symptoms experienced by heart failure patients many report increased confusion (Nordgren, Sörensen 2003) and memory impairment. There is some evidence of heart failure being associated with effects on cognitive function.(Taylor, Stott 2002, Vogels et al. 2007) In an interview study 12 weeks after hospital admission more than half the patients interviewed reported loss of memory for recent events.(Lainscak, Keber 2003)

In right sided heart failure congestion affects the liver, gastrointestinal tract and the limbs resulting in the most common symptoms of ankle swelling and fatigue. Gastrointestinal symptoms are also prominent and include anorexia, nausea, constipation and occasionally abdominal pain. Breathlessness is a less common feature in right sided heart failure compared to left sided heart failure but may occur in the latter stages when cardiac output is severely compromised.

As clinical presentation differs depending on the degree of left sided or right sided failure, symptoms in heart failure patients are usually graded by a functional classification. The New York Heart Association (NYHA) Classification of Heart Failure is the most widely used functional classification used in clinical practice and in research to assess heart failure symptom severity.

The NYHA developed its first classification to grade clinical severity of heart failure in 1928. The classification has been amended and updated many times since then. The latest edition was revised by the Criteria Committee of the American Heart Association in 1994 and is outlined in Table 1.

New York Heart Association (NYHA) Classification	
Class I	Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnoea or angina symptoms.
Class II	Patients with cardiac disease resulting in slight limitation of physical activity. Ordinary physical activity results in fatigue, palpitation, dyspnoea or angina symptoms.
Class III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnoea or angina symptoms.
Class IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the angina may be present even at rest. If any physical activity is undertaken, discomfort increases.

Table 1

New York Heart Association (NYHA) Classification, adapted from (Butler 2007)

As outlined in Table 1, the NYHA classification has four functional classes which grade the severity of heart failure. In clinical practice, class I and II will generally include patients with mild symptoms, while class III and IV indicate moderate to severe heart failure. The NYHA is a useful assessment tool as it provides a standardised description of severity that can be used to assess the impact of heart failure on a patient's functional ability as well as the response to any treatments administered. The NYHA classification does not always reflect heart failure severity due to the variation in patients' perception of symptoms and function and the fluctuation in symptoms of heart failure. This limits its use in predicting prognosis.

Investigation and Diagnosis in General Practice

The clinical diagnosis of heart failure is difficult in general practice. Patients with heart failure may present with non-specific symptoms and may have co-existing conditions which have similar symptom profiles. The accurate diagnosis of heart failure is becoming increasingly important with the development of medical and surgical interventions which can improve patient outcomes. There is evidence that general practitioners have high false positive rates when diagnosing heart failure clinically. (Sparrow et al. 2003) The UK National Service Framework therefore recommends all patients with suspected heart failure undergo echocardiography.(Department of Health 2000)

The National Institute for Clinical Excellence issued guidance on the investigation of heart failure in general practice in July 2003. The algorithm in Figure 3 illustrates the current appropriate investigation of a patient presenting to general practice with symptoms of heart failure. The guidelines recommend that a 12-lead electrocardiogram, a chest X-ray, haematological and biochemical investigations should be initiated in general practice for patients with suspected heart failure.(National Institute for Health and Clinical Excellence 2003) Although these investigations indicate if heart failure is a probability and exclude other conditions, they do not establish a diagnosis and their contribution to assessment of severity of heart failure is limited.

Natriuretic peptides are a more recent development in the investigation of suspected heart failure patients. The presence of a raised concentration, particularly of the B-type natriuretic peptide, has been shown in studies in both primary and secondary care to provide an indication of left ventricular dysfunction.(Mant, Hobbs & Glasziou 2008, Maisel et al. 2002, Cowie et al. 1997)

However natiuretic peptide levels may be elevated in other conditions such as hypoxaemia, renal failure, liver cirrhosis and sepsis. A study of 621 patients in general practice found evidence of poor overall diagnostic accuracy of BNP when compared to echocardiography.(Sparrow et al. 2003)

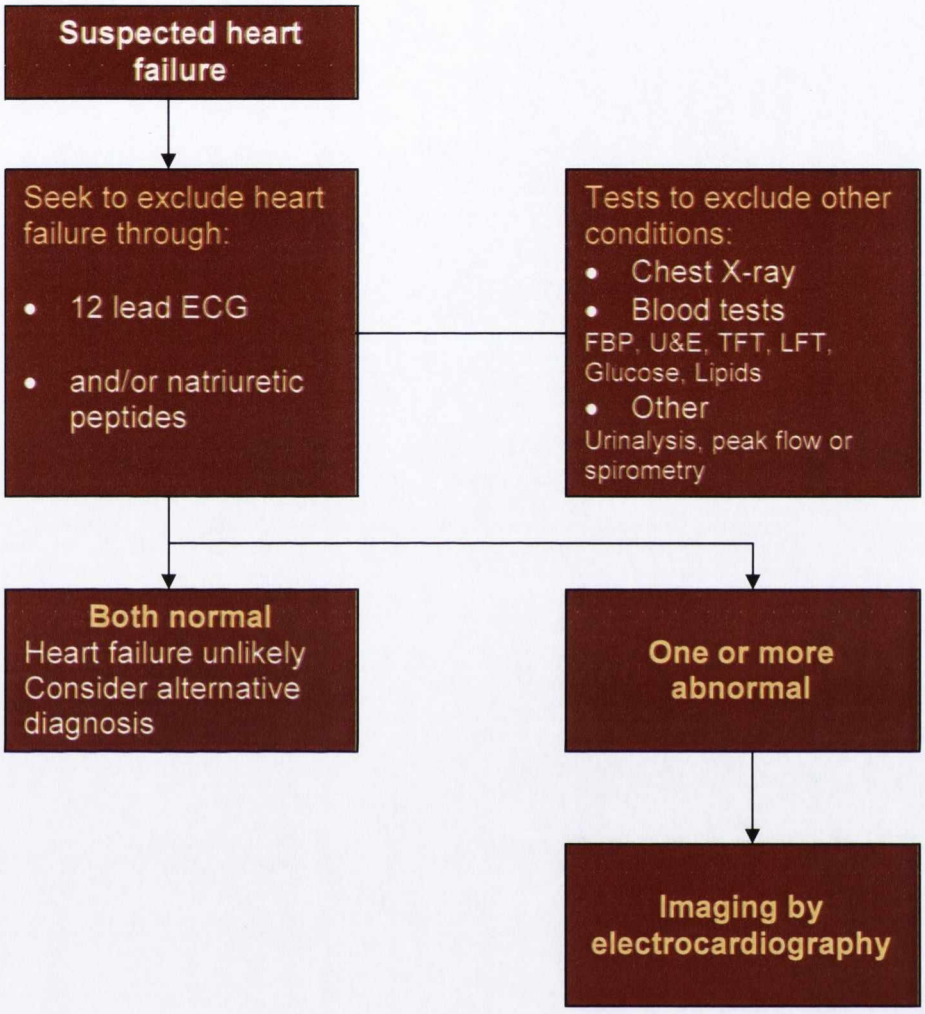

Figure 3

The investigation of suspected heart failure in General Practice, adapted from Management of chronic heart failure in adults in primary and secondary care. National Institute for Health and Clinical Excellence, Inherited Clinical Guideline 5, July 2003.

The introduction of the echocardiogram was a key turning point in the diagnosis and investigation of heart failure and it remains the most commonly used diagnostic tool today.(Davis, Hobbs & Lip 2000)

Management of heart failure in General Practice

Heart failure can be managed using three main treatment modalities, non-pharmacological, pharmacological and surgical interventions. The main aims of treatment are symptom control, delayed progression of disease, reduction in hospital admissions, extension of life and improvement in quality of life.
In primary care the mainstay of heart failure treatment involves a combination of non-pharmacological and pharmacological therapies. Surgical interventions only apply to specific patients and these are confined to secondary care.

Non-pharmacological treatments are an important adjunct to pharmacological treatments in heart failure. Examples of these are dietary adaptations such as reduction of salt, fluid and alcohol, exercise rehabilitation programmes, psychological interventions, and patient education, which can be used when appropriate.

NICE issued guidelines in the management of chronic heart failure in adults in primary and secondary care in 2003. The main groups of drugs used in the treatment of heart failure are shown in the algorithm (Figure 4) adapted from these guidelines. Angiotensin converting enzyme (ACE) inhibitors are the first line treatment and have been shown in many large randomised trials to improve both morbidity and mortality.(The CONSENSUS Trial Study Group 1986, The Study of Left Ventricular Dysfunction (SOLVD) Investigators 1991) The major

adverse effects of ACE inhibitors include cough, hypotension, hyperkalaemia, renal disturbance and allergic reactions. The Angiotensin 2 receptor antagonists are similar to the ACE inhibitors but have the advantage of being able to be administered to patients who develop side effects such as cough with ACE inhibitors.

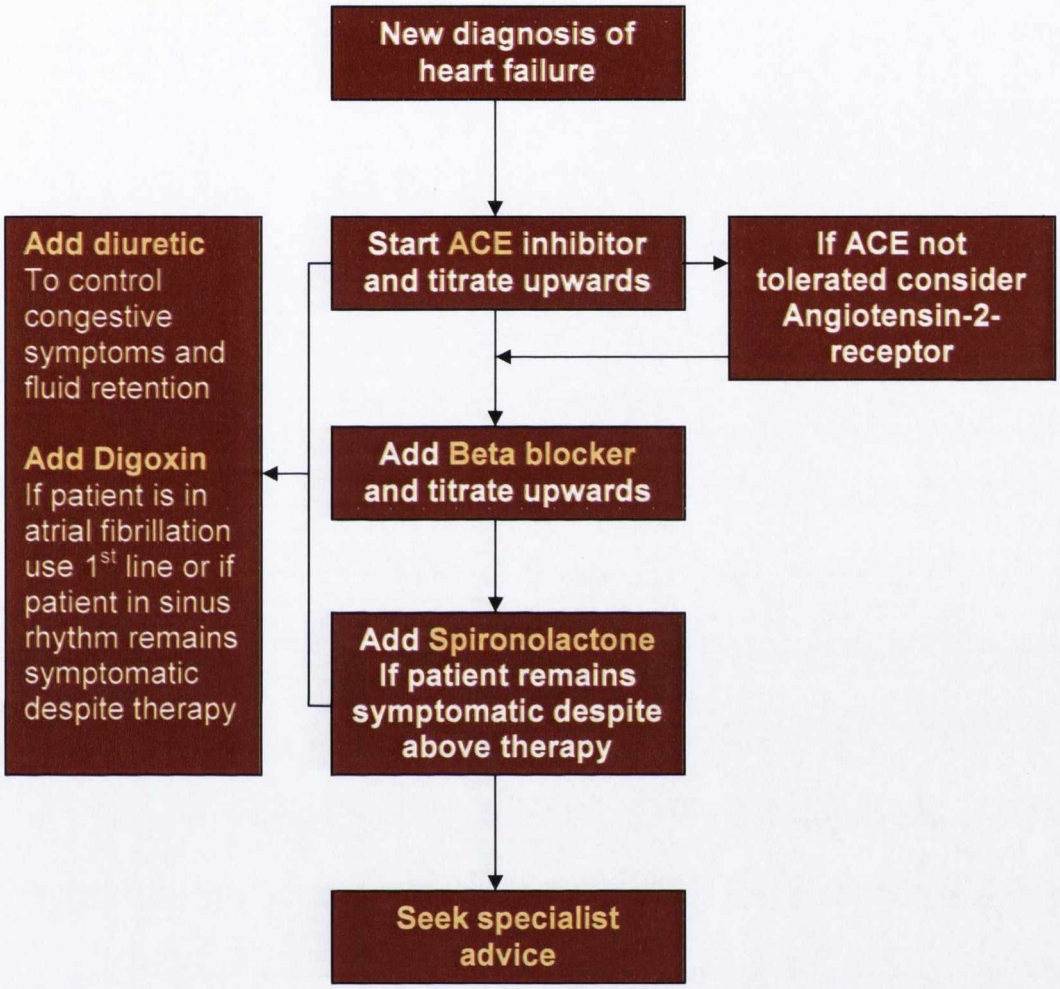

Figure 4

Pharmacological treatment of heart failure in General Practice, adapted from Management of chronic heart failure in adults in primary and secondary care. National Institute for Health and Clinical Excellence, Inherited Clinical Guideline 5, July 2003.

Despite being negative inotropes, beta blockers are beneficial in heart failure management. The study CIBIS-I found that the introduction of bisoprolol to traditional heart failure therapy resulted in a reduction in hospital admissions.(CIBIS Investigators and Committees 1994) The follow on study CIBIS-II confirmed this and also showed reduced mortality rates in patients treated with beta blockers. (Thomas 2000) As a result it is now recommended that beta blockers should be added following titration of an ACE inhibitor. In clinical practice this tends to be performed under specialist supervision in secondary care.

Diuretics are useful for control of symptoms such as breathlessness due to lung congestion and peripheral oedema, however there is no evidence of improved survival with these medications. Digoxin is also used as an adjunct, particularly in patients with co-existing atrial fibrillation but evidence to date does not show any reduced mortality with the use of digoxin in heart failure.

As with other chronic diseases, it is important when treating patients with heart failure that a holistic approach to treatment is adopted. An improvement in physical symptoms may be achieved by following the guidance on pharmacological management but patients will often have psychological and social needs which also need addressed in primary care.

Mortality and prognosis in heart failure

Follow up of patients in the Framingham study identified very high mortality rates in heart failure patients when compared to other chronic diseases.(Ho et al. 1993a) The median survival following diagnosis of heart failure from this study was shown to be only 1.66 years in men and 3.17 years in women.(Ho et al. 1993a)

Heart failure, in its later stages, also carries a worse prognosis than most cancers. A population based study comparing heart failure and cancer survival highlighted the high mortality in heart failure. Heart failure patients had a poorer 5 year survival rate than all the cancers studied except for lung cancer and this lead to the description of heart failure as "more malignant than cancer". (Stewart et al. 2001) In a Norweigan study investigating symptoms experienced by heart failure patients in the last six months of life, breathlessness, ankle swelling, fatigue and limitation in physical activity were the most commonly reported symptoms. (Nordgren, Sörensen 2003) This study was preceded by the RSCD – Regional Study of Care for the Dying, 1996 which interviewed carers of patients who had died from heart disease. (McCarthy, Lay & Addington-Hall 1996) Pain was the most common symptom reported in this study, followed by dyspnoea. Both these studies highlight that the symptoms experienced by heart failure patients are very similar to those described by cancer patients. However the studies were both retrospective and the findings are limited due to potential recall and reporting bias. The RSCD relied on carers recalling symptoms 10

months after death while the Norweigan study relied on reporting of symptoms in patients' records. This study recognised the need for further qualitative research to determine the views of these patients in order to improve care in end-stage heart failure. (Nordgren, Sörensen 2003)

Despite having similar prognostic outcomes and patients reporting similar symptoms, the end-stages of heart failure and cancer may vary. The disease trajectory in heart failure is less predictable than in cancers and can be highly variable. (Lunney et al. 2003, Gott et al. 2007). Patients may experience a chronic decline but acute exacerbations with subsequent recovery are a feature of heart failure, as is sudden death with no preceding decline in function.(Uretsky, Sheahan 1997) This leads to difficulties in estimating prognosis and instigating appropriate care, particularly in general practice.

Palliative care in heart failure

The symptoms experienced by patients with end-stage heart failure are distressing, poorly controlled and similar to those of patients dying of cancer.(McCarthy, Lay & Addington-Hall 1996) The difficulty in predicting prognosis is one of the barriers to referring heart failure patients for palliative care.

By definition palliative care is the active, holistic care of a patient with advanced, progressive illness. (Nordgren, Sörensen 2003) Palliative care aims to improve the quality of life for patients and their families facing life-threatening illness by identifying their physical, psychological and spiritual problems and treating these accordingly. (World Health Organisation 2007) Traditionally the use of palliative and supportive care has been associated with patients who have a cancer diagnosis. However, the need for this type of care provision to be extended to chronic illnesses, such as heart failure, is now recognised. (Ward 2002)

The Gold Standards Framework (GSF) is an evidence (Thomas 2000) based guideline which aims to optimise the care for patients nearing the end of life in the community. This guideline recognises the need to identify patients with non-cancer conditions who require palliative care input. The GSF has developed criteria to enable identification of heart failure patients with palliative care needs:

- Patient in NYHA class III or IV
- Patient thought to be in the last year of life
- Patient who has been admitted to hospital frequently with heart failure symptoms
- Patient with difficult physical or psychological symptoms despite optimal medical therapy

In general practice these criteria can be used to identify heart failure patients and, using the palliative care model, address their physical, psychological and social needs with the ultimate aim of improving quality of life.

Chapter 2 - Quality of life in heart failure patients: a literature review

What is quality of life?

In treating heart failure health professionals aim not only to relieve symptoms and prolong life, but also to improve quality of life. Traditionally the outcome measures used in clinical trials in heart failure have been confined to exercise capacity, recurrent hospitalisation, left ventricular ejection fraction and death. However, quality of life is becoming increasingly recognised as a potential end-point for intervention trials in heart failure.

Quality of Life (QOL) is defined by the World Health Organisation as a "state of complete physical, mental and social well-being and not merely the absence of disease". (Cella 1994) In contrast to this, health-related quality of life (HRQL) represents a patient's satisfaction with the domains of life as affected by health or the difference between an individual's current function and their expected health status. (Masoudi et al. 2004)

" The terms quality of life and more specifically health related quality of life refer to the physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions." (Testa, Simonson 1996) As a result there are an infinite number of

states of quality of life. The effect of disease on quality of life is highly individual dependent. For example two patients of the same age, social circumstances and similar symptoms of disease may perceive their quality of life very differently due to the influence of their experiences, perceptions, beliefs and particularly – their expectations.

Patients with heart failure may have significant functional limitations.(Stewart et al. 1989) Functional status reflects the ability to carry out tasks or everyday functions without significant limitation. This may include physical, social, and mental functions.

There is no agreed definition of what constitutes the domains which contribute to quality of life. It is believed that many factors may exert an influence on an individual's quality of life and many conceptual frameworks exist. Models commonly include domains such as physical, psychological and spiritual health, each of which may have many sub domains. The World Health Organisation has produced generic quality of life instruments, developed simultaneously in 15 field centres around the world, known as the WHOQOL. In the development of these instruments they identified important aspects of quality of life on the basis of statements made by:

- Patients with a range of diseases
- Well people
- Health professionals

The background research was performed in a variety of cultures and the instrument was rigorously tested to assess its validity and reliability in each of the field centres. Six broad domains of quality of life, and twenty-four facets were identified in the rigorous development of these quality of life questionnaires. The table below (Table 2) has been adapted to illustrate these domains and facets of quality of life.

Domain	Facets incorporated within domains
(1) Physical health	• Energy and fatigue • Pain and discomfort • Sleep and rest
(2) Psychological health	• Bodily image and appearance • Negative feelings • Positive feelings • Self-esteem • Thinking, learning, memory and concentration
(3) Level of Independence	• Mobility • Activities of daily living • Dependence on medicinal substances and medical aids • Work capacity
(4) Social Relations	• Personal relationships • Social support • Sexual activity
(5) Environment	• Financial resources • Freedom, physical safety and security • Health and social care: accessibility and quality • Home environment • Opportunities for acquiring new information and skills • Participation in and opportunities for recreation/leisure • Physical environment (pollution/noise/traffic/climate) • Transport
(6) Spirituality/ Religion/ Personal Beliefs	• Religion/Spirituality/Personal beliefs (Single facet)

Table 2

Quality of life domains and facets. Adapted from the World Health Organization (1993). WHOQoL Study Protocol.

Quality of life in heart failure: the evidence

The detrimental effects of heart failure on quality of life have been recognised as early as 1963 when physical and mental stress were identified in end-stage heart failure patients in a London hospital.(Hinton 1963) More recently the Medical Outcomes study (Stewart et al. 1989) assessed quality of life in 9385 patients with various chronic diseases. Patients with heart failure showed significant impairment in the physical and mental health domains and those with advanced heart failure had similar scores to patients with major depression measured on mental health scales. (Stewart et al. 1989) Heart failure patients have poorer quality of life than those with other chronic diseases such as hypertension, diabetes and chronic lung disease.(Stewart et al. 1989, Hobbs et al. 2002)

A literature review on the effect of quality of life in heart failure was performed using the keywords 'heart failure', 'quality of life', and 'health related quality of life'. The database Medline was used for the searches and searches were combined to identify literature which contained both the keywords 'heart failure and quality of life' or 'heart failure and health related quality of life'. Articles were examined for suitability and references in the individual articles were also

explored. The original search was performed in August 2007 and repeated at intervals until May 2009 to identify any additional publications.

The generic framework of domains and facets which contribute to quality of life, such as the WHO outline, (Table 2) can also be applied to heart failure patients. In addition disease specific conceptual models have been developed to explain the interaction between disease and quality of life. The flowchart in Figure 5 was developed by Thomas Rector, one of the authors of the Minnesota Living with Heart Failure quality of life questionnaire. The flowchart illustrates how symptoms of heart failure may directly impact quality of life and the concept that the effect of these symptoms in terms of functional limitation and psychological distress can also impair quality of life. This conceptual model however lacks the detail of individual quality of life domains shown in Table 2 and also does not account for variation in individuals e.g. personality traits, personal circumstances and spirituality.

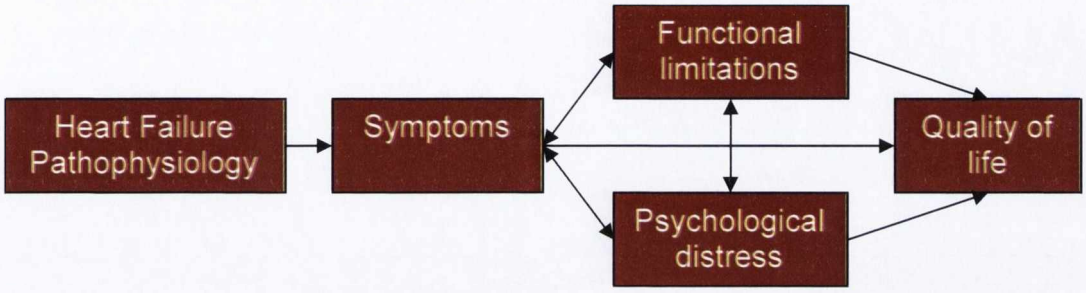

Figure 5

Conceptual model of the relationships between heart failure pathophysiology, symptoms, functional limitations, psychological distress and quality of life. Taken from (Rector 2005)

Symptoms and quality of life

In further work Rector et al tested the conceptual model (Rector, Anand & Cohn 2006) and found that symptoms of heart failure alone explained 41% of the variation in the effects of heart failure on quality of life. The authors used data from the Valsartan Heart Failure trial (Rector, Anand & Cohn 2006, Rector, Kubo & Cohn 1987) to assess the contribution of symptoms such as dyspnoea on rest and exertion, paroxysmal nocturnal dyspnoea, orthopnoea, fatigue and New York Heart association class on quality of life scores as measured by the Minnesota Living with Heart Failure questionnaire (MLwHF). Fatigue explained 38% of variation in MLwHF scores with dyspnoea explaining 28% of the variation. The other symptom based variables exerted a less significant effect on variation in quality of life scores however patient demographics also contributed to the variation of quality of life a small degree.

Heart failure patients report a wide range of symptoms. A sample of 60 hospital outpatient heart failure patients had a mean of 9 symptoms, measured using the Memorial Symptoms assessment Scale-Short form. In this cohort of patients as symptoms increased, disease specific quality of life decreased and symptoms accounted for 32% of the variance in quality of life. This study also explored the relationship between depression and quality of life and found that the presence of depression was associated with higher reporting of symptoms and poorer quality of life. (Bekelman et al. 2007)

The importance of symptomatic heart failure on quality of life as opposed to the diagnosis alone was highlighted by the ECHOES study group.(Hobbs et al. 2002) They used the SF-36 on patients referred from the community for assessment of heart failure. The quality of life scores of those who were diagnosed as having heart failure (n= 426) were compared with the outcomes for the patients who did not have heart failure (n=3850). A significant impairment was noted in physical and mental health of the heart failure patients when compared to the normal population. However those with asymptomatic heart failure had similar scores to the population sample, highlighting the impact of the symptoms rather than the disease itself on quality of life. (Hobbs et al. 2002)

The symptoms experienced by heart failure patients may differ according to stage of disease. In a retrospective review of the medical records of patients with end stage heart failure, patients reported an average of 6.7 symptoms. Breathlessness was the most common symptom, pain the second most frequent and fatigue the third most common symptom. (Nordgren, Sörensen 2003) Pain is a symptom which is expected in cancer patients nearing the end of life but would not be a typical symptom of heart failure. It was however found to be a problem in the last six months of life in 78% of the patients studied in the Regional study of care for the dying (Addington-Hall, McCarthy 1995) including patients with heart failure.

Disease severity and quality of life

The stage or severity of heart failure and its impact on quality of life have been studied at length in secondary care. Most studies use a functional classification such as the NYHA classification or an objective measure of failure severity such as left ventricular ejection fraction. Irrespective of the grading system used, increasing heart failure severity has been found to be associated with significantly poorer quality of life. (Hobbs et al. 2002, Azevedo et al. 2008, Juenger et al. 2002, Gott et al. 2006) It could be argued however, that by using a classification like the NYHA class to define heart failure severity and asking patients which group they fall into is an indirect reflection on their perception of their quality of life. Therefore the researchers may be measuring the same construct.

Psychological health and quality of life

In addition to multiple physical symptoms heart failure patients may suffer impairment of quality of life through psychological distress. The medical outcomes study reported high levels of depression in patients with heart failure. (Stewart et al. 1989) Other studies have found that the levels of psychological distress in heart failure are comparable to that of cancer. (Addington-Hall, McCarthy 1995) and the impact of depression on quality of life is known to be associated with higher mortality in heart failure.(Murberg et al. 1999)

Psychological distress in patients with heart failure in primary care may be under-diagnosed. Patients with heart failure recruited from general practice in Germany completed the Hospital Anxiety and Depression scale, a disease specific quality of life instrument and a 'coping with illness' questionnaire at baseline and then 9 months later. Higher levels of psychological dysfunction (depression and/or anxiety measured by the HADS) were observed in patients with higher NYHA class and in those with background emotional problems. Positive influences on psychological health included the presence of social support and living with a partner. (Scherer et al. 2007) Psychological distress has a significant association with quality of life. Rector's conceptual model recognises this association and studies have shown that psychological ill-health leads to poorer quality of life in patients with heart failure. (Bekelman et al. 2007, Azevedo et al. 2008, Scherer et al. 2007)

Patient characteristics and quality of life

The effect of demographic factors on quality of life may vary depending on the disease being studied. In heart failure the influence of patient demographic factors on quality of life in secondary care patients is well reported although conflicting evidence exists. Azevedo et al reported poorer quality of life in older patients using the SF-36. (Azevedo et al. 2008) However, a multicentre prospective cohort study assessing how age and functional capacity impact upon quality of life showed that older age was independently correlated with better HRQL. At baseline in this study older patients had better quality of life scores, measured by the Kansas City Cardiomyopathy Questionnaire, than younger patients despite having poorer levels of functional capacity. (Masoudi et al. 2004) In a study looking at symptoms and quality of life, demographic factors such as race, gender and co-morbidity explained less than 1% in the variation in quality of life but age explained an additional 4.5% in variation. (Rector, Anand & Cohn 2006)

Women with heart failure appear to have lower quality of life scores than men in hospital based studies (Azevedo et al. 2008) and in heart failure patients recruited from primary care (Gott et al. 2007). No studies identified from the review reported any significant differences in men and women in terms of age or disease severity, therefore it is not known why gender in heart failure patients should influence quality of life.

Evidence also suggests that marital status has an effect on both heart failure prognosis (Rohrbaugh, Shoham & Coyne 2006) and quality of life (Scherer et al. 2007). Relationship quality has been shown to be a predictor of 8-year survival, especially in female heart failure patients (Rohrbaugh, Shoham & Coyne 2006).

Heart failure patients will often have multiple co-morbid conditions. Bekelman et al recognised the potential influence of co-morbidity on symptoms in heart failure patients.

"Many of the symptoms reported are not generally thought of as being caused by heart failure... (they) may be associated with co morbid illnesses..." (Bekelman et al. 2007)

The effect of co-morbid conditions on quality of life in heart failure patients varied in different studies. Levels of co-morbidity are generally thought to be associated with impairment in health related quality of life.(Gott et al. 2006) Rector et al found in their study that the variation in quality of life scores explained by co-morbidity was less than 1%, (Rector, Anand & Cohn 2006) however the co-morbid conditions studied were limited to ischaemic heart disease, hypertension, diabetes and atrial fibrillation.

Quality of life of heart failure patients in General Practice

Most of the quality of life data for patients with heart failure has been obtained from trials in secondary care. Older patients are under-represented in these trials. Women and those with co-morbidity are also under-studied. (Heiat, Gross & Krumholz 2002, Krumholz 1998, Masoudi et al. 2003)

There are a few studies reporting the impact of heart failure on quality of life within community settings. This limits the relevance of existing quality of life data to patients being managed in the community.

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Two studies have explored quality of life in patients recruited from primary care. The ECHOES study (Hobbs et al. 2002) recruited patients from primary care and through screening with echocardiography identified heart failure patients and used the SF-36 to measure their quality of life. Patients over the age of 45 were randomly selected from 16 general practices in the West Midlands and NYHA grading was performed by a consultant. This study showed the heart failure patients had significant impairment in quality of life compared to those without heart failure and that NYHA class was associated with SF-36 score. However the study used a generic quality of life measure rather than a disease specific measure and demographic characteristics of patients were not considered.(Hobbs et al. 2002)

A prospective postal questionnaire survey performed in general practice in four areas of the United Kingdom recruited a total of 542 patients over the age of 60 years with heart failure. (Gott et al. 2006)Factors found to be associated with a decreased quality of life in heart failure patients included:

- Female gender
- New York Heart Association (NYHA) functional class 3 or 4
- Evidence of depression
- Lower socioeconomic status
- Experiencing two or more co-morbidities. (Gott et al. 2006)

The data collection for this study was performed prior to the introduction of the Quality and Outcomes framework for General Practice and therefore recruitment of patients was more difficult. The researchers used disease codes and medications used in heart failure to identify patients. GPs then excluded patients if they felt they did not have heart failure. The evidence used in their decision was not specified and may have been inconsistent as patients may have a clinical diagnosis of heart failure, but not necessarily a diagnosis confirmed by echocardiogram. This study used two quality of life instruments, a generic tool (SF-36) and a disease specific instrument (the Kansas City Cardiomyopathy Questionnaire). Using these two measures added strength to their findings however the age group was limited to those over 60 years so the results cannot

be used to make assumptions regarding the quality of life of younger patients in the community.

Quality of life has been shown to be a reliable predictor of mortality and hospitalisations in heart failure patients.(The Study of Left Ventricular Dysfunction (SOLVD) Investigators 1996) In addition knowledge of quality of life in heart failure patients is important for physicians in order to improve patient care. Further research is required in general practice as the evidence available has limitations and may not be applicable to certain age groups and other populations, such as Northern Ireland.

Qualitative research in heart failure

"Qualitative research is multi-method in focus, involving an interpretive, naturalistic approach to its subject matter. This means that qualitative researchers study things in their natural settings, attempting to make sense of, or interpret, phenomena in terms of the meanings people bring to them." (Wilems et al. 2006)

Qualitative research is an ever increasing method of data gathering in health care research. It aims to explore patients' experiences, ideas, processes and or beliefs in the particular area of interest. Qualitative methods may be used in isolation or combined with other forms of research methodology.

Qualitative data may be gathered in many ways. In health care research data are usually obtained through interviews and or focus groups. Other types of qualitative data include open comments in questionnaires, case study notes, and minutes of meetings, personal documents and even visual material such as photographs.

Qualitative research can answer questions which are beyond the realms of quantitative research. It can describe, explain and attempt to understand a particular research question and can inform us as health care providers how various diseases impact on the individual rather than the general population.

Despite this, qualitative research is not without rigour. Quantitative research achieves scientific rigour through validity, reliability, objectivity and generalisability. The scientific rigour in quantitative research is achieved through the processes of credibility, fittingness, auditability and confirmability. (Wilems et al. 2006) Credibility describes the extent to what findings and interpretations are credible with the sources from which they are drawn while fittingness refers to how the study context fits with the practice context. The ability to follow the data analysis process or decision trial is auditability and if another researcher is able to arrive at the same conclusions the data is confirmable.

The impact of chronic disease on patients' everyday lives is a good example of how qualitative research is useful in healthcare. Studies gathering data on the drug treatments used in heart failure and how they affect quantitative outcomes e.g. symptoms scores or six minute walk tests, are abundant. These are very useful in evidence based practice and can improve patient outcomes but they tell little of the health related issues which are important to the patients themselves. To find out this information it is necessary to use qualitative methods.

Living with heart failure

A study explored the perceptions of patients with end stage heart failure regarding the 'work' of every-day living. The authors interviewed 31 patients with NYHA stage III or IV heart failure at baseline and conducted follow up interviews at 3-5 month intervals. Their objective was to explore how these patients lived and what work was involved in this, regardless of any work related to paid employment. Using a prospective longitudinal design, semi-structured interviews were performed until data saturation was reached. The following domains were used to categorise potential areas of patient work in heart failure:

- Managing the illness
- Everyday work to keep life going
- Biographical work
- Arrangement work

Patients reported work organising medications and fluid intake as main tasks in management of their illness. They felt having to be organised and strict in timing of activities was restrictive. They also described how fatigue dominated daily life to the extent that every-day activities such as eating, bathing and going to the toilet had become so energy consuming that they became serious work. Loss of social activities and being unable to attend events was the main limitation in biographical work while household adaptations and the effort to obtain these

required arrangement work. (Wilems et al. 2006) This information is vital in understanding how patients perceive work due to their condition. This type of data and level of detail could not be achieved through quantitative means.

Patient's perception of quality of life – qualitative view

Heo et al (Heo et al. 2009) used a qualitative approach to explore how patients with heart failure defined and perceived quality of life. Through semi-structured open-ended interviews with 20 heart failure patients the most common definition of quality of life from the patient's perspective was "the ability to perform physical and social activities". Content analysis of the interviews revealed that patients identified three key components of quality of life:

1. Performing physical and social activities
2. Maintaining happiness
3. Engaging in fulfilling relationships

Certain influences were noted to have negative or positive effects on quality of life including physical factors such as symptoms, physical status, psychological factors such as mood, perspective and social factors such as social support and ability to perform social activities. Spiritual, behavioural and economic influences were also identified as having potential positive or negative effects. This study is important as few investigators have examined quality of life from the heart failure patient perspective. However a convenience sample of patients who lived in a Midwestern city in the United States was used in this study and the average age of the study participants was 58 years with 70% of them men. This data therefore may not reflect the opinions of other heart failure patients as the sample was predominantly male and this cohort of patients is much younger

than the general heart failure patient population.(Heo et al. 2009) Bosworth et al (Bosworth et al. 2004) also used qualitative methods to investigate how patients with heart failure perceived quality of life and in particular, its components. They used focus groups and identified five quality of life domains: symptoms, role loss, affective response, coping, and social support. Participants in this study reported worries for their family and the uncertainty of prognosis as areas of concern. (Bosworth et al. 2004)

Unmet needs in heart failure

As previously discussed, patients with heart failure have a similar prognosis to many cancer patients and share common symptoms towards the end of life. The disease trajectory of heart failure is less certain and this is a potential barrier for the introduction of palliative care to these patients. The principles of palliative care allow a holistic care approach with tailoring to the individual's needs. Without palliative care input, this may be absent and as a result patients may have unmet needs. In chronic illness, like heart failure, deteriorating health status, decreased independence and social isolation are problems that patients may report.(Fitzsimons et al. 2007) Some needs which have been identified through qualitative interviews include:

- Physical needs e.g. deteriorating health status and limited resources
- Emotional needs e.g. worries and concerns for the future
- Social needs e.g. lack of social support

The authors of this study recognised that the needs of patients with advanced chronic illness are complex and a more-timely implementation of palliative care is necessary in order to meet these needs.(Fitzsimons et al. 2007) Further research in this area, particularly concentrating on heart failure patients in isolation, would be necessary in order to improve their care.

Quality of life in heart failure: conclusion

Heart failure is a complex clinical syndrome which has high levels of morbidity, mortality and, like other chronic diseases, can detrimentally affect quality of life. There is conflicting evidence of the variables which affect the quality of life in heart failure patients. Most of the evidence to date has been gathered from clinical trials in secondary care using selected, hospital based patients. This does not represent the typical heart failure population seen by a general practitioner. As increasing numbers of heart failure patients are now being managed in the community and information on their quality of life is limited, it is imperative that further research in this area is performed. The impact of heart failure on quality of life cannot be observed directly, to measure this it is necessary to use a quality of life instrument or gather information from the patient's perspective.

Chapter 3 - Measuring quality of life in heart failure

Measuring quality of life using questionnaires

Quality of life can be described as both subjective and multidimensional. (Cella 1994) It is subjective as it can only be measured from the patient's perspective and multidimensional as in order to assess it information must be gathered from various aspects of the patient's life. (Cella 1994)

Quality of life questionnaires aim to gather information from the patient's perspective, measuring various domains, and translate this into a quality of life scale score. This information can be used to assess the impact of a disease on an individual, as well as determining the success of a particular intervention in research or clinical practice.

There are many different types of quality of life questionnaires. The output and its relevance will be influenced by the degree of objectivity of the dimensions measured, the emphasis on various domains, and the format of the questionnaire. The degree to which various components or domains are included will depend on the patient population on which the questionnaire is to be used. However despite variation to truly measure health related quality of life, an instrument must evaluate physical, emotional and social well-being.

Questionnaires should also show evidence of:

- Reliability — The outcome is consistent with repeated measurements
- Validity — The tool measures what it claims to measure
- Responsiveness — It is able to detect true changes or differences

Quality of life questionnaires used in health care research generally fall into one of two groups: generic or disease specific instruments.

Generic quality of life instruments

Generic quality of life questionnaire are designed to be broadly applicable across diseases and health conditions, they are not specific to any particular disease or population of patients. They should summarise health across various aspects of quality of life and be applicable to a wide range of healthcare interventions. The strength of generic quality of life tools is their use in conducting general research or making comparisons on quality of life in differing subsets of patients. They are less useful in gaining detailed quality of life data in patients with a particular condition.

There are a wide variety of generic quality of life instruments available. The Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, the Nottingham Health Profile (NHP), the Sickness Impact Profile (SIP), the Dartmouth Primary care Cooperative Information Project (COOP) Charts, the Quality of Well-Being (QWB) Scale, the Health Utilities Index (HUI), and the EuroQol Instrument (EQ-5D) are the most commonly used in the English language literature.(Coons et al. 2000) Of the instruments reviewed for this study, the SF-36 Health Survey was the most commonly used generic quality of life measure.

The Short-Form 36 and Short-Form 12

The Medical Outcomes study 36-Item Short Form Health Survey (SF-36) is a generic questionnaire developed which demonstrates a high degree of internal consistency and test –retest reliability. (Stewart et al. 1989) It is well validated in a variety of patient groups and is comparable to the Nottingham Health Profile (NHP). (Brazier, Harper & Jones 1992) The SF-36 discriminated between heart failure patients and those with other chronic diseases in the Medical Outcomes study. It does however have some limitations. For example, it does not cover the area of sleep disturbance. (Berry, McMurray 1999). It is also lengthy and potentially difficult to complete, and as a result it has poor response rates in the elderly. (Jenkinson, Layte & Jenkinson 1997)

A shortened version of the SF-36 is available in the form of the Medical Outcomes Study 12-Item Short Form (SF-12). The SF-12 is a 12 item-instrument consisting of two major summary scales, the physical component scale (PCS) and the mental component scale (MCS). The SF-12 has comparable validity to the SF-36. (Ni et al. 2000) The two measures have been compared in different patient groups, including a study of patients with heart failure. (Jenkinson, Layte & Jenkinson 1997) The SF-12 has also been compared to the disease specific tool, the Minnesota Living with Heart Failure questionnaire (MLwHF). (Ni et al. 2000) In this prospective cohort study of heart failure patients attending a university-based clinic the SF-12 was more sensitive to changes in physical health but less sensitive to changes in mental health. The

MLwHF was more sensitive to changes overall. As a result the SF-12 in isolation is not recommended for detecting changes in quality of life in heart failure patients. If a generic quality of life measure is appropriate it should be combined with other qualify of life instruments which are sensitive to change. (Ni et al. 2000)

Disease specific quality of life instruments

A disease specific quality of life questionnaire is designed to be used in a specific condition or patient population. The domains included will be selected for their relevance and to cover the typical symptoms of the condition. Disease specific quality of life questionnaires will be piloted and validated in their target population, therefore they usually cannot be applied to other populations as the validity in these populations will be unknown. The strength of disease specific quality of life tools is their use in conducting research on quality of life or evaluating the effect of a therapeutic intervention in patients with a certain condition. Their main limitation is the narrow range of application.

Disease specific questionnaires used in heart failure have been designed to assess symptoms and other domains of quality of life that are typically affected by the condition. The most commonly used disease specific questionnaires developed for use in heart failure patients are the Minnesota Living with Heart Failure Questionnaire (MLwHF), the Chronic Heart failure Questionnaire (CHFQ), the Quality of Life Questionnaire for Severe Heart Failure (QLQ-SHF), the Kansas City Cardiomyopathy Questionnaire (KCCQ) and the Left Ventricular Dysfunction (LVD-36) questionnaire.

The Minnesota Living with Heart Failure questionnaire (MLwHF)

The Minnesota Living with Heart Failure questionnaire (MLwHF) was developed in 1984 by Rector et al. (Rector, Kubo & Cohn 1987) It consists of 21 questions assessing physical symptoms and signs, physical functioning, social functioning, emotional functioning, sexual functioning and ability to work. Questions are answered on a Likert type scale ranging from 0 which represents 'no' to 5 which corresponds to 'very much'. The total score for the questionnaire is calculated by adding the individual question scores with a possible range of 0 to 105. A Physical dimension scale can be obtained by summing the individual scores from questions 2, 3, 4, 5, 6, 7, 12, and 13. The possible range for the physical dimension score is 0 to 40. An emotional dimension scale can be obtained by summing the individual scores from questions 17, 18, 19, 20 and 21. The range for this dimension is 0 to 25.

The MLwHF is well validated in trials assessing baseline quality of life characteristics (Gorkin et al. 1993), pharmacological (Rector, Cohn 1992) and non-pharmacological interventions. (Smith et al. 1997)

Comparisons of quality of life measures used in heart failure

A literature review was performed to find literature comparing quality of life measures used in heart failure populations through the Medline database. The keywords used were 'quality of life', 'questionnaires', 'compare', and 'heart failure'. The search results were examined for appropriate individual studies, review articles, systematic reviews and meta-analyses. A total of five documents were identified as relevant, two review articles comparing the generic and disease specific measures used in heart failure research, one systematic review with meta-analysis of disease specific measures only, and two studies comparing the MLwHF and the Short Form questionnaires.

In the first review article (Berry, McMurray 1999) the authors reviewed the design and validation literature for use of the following generic and disease specific questionnaires in patients with heart failure, the Sickness Impact Profile, the Short Form 36, the Nottingham Health Profile, the Quality of Wellbeing Scale, the Minnesota Living with Heart Failure questionnaire, the Quality of Life in Severe Heart Failure questionnaire and the Chronic Heart Failure questionnaire. They found inconsistent performance and sensitivity in all the questionnaires studied. The SF-36 and the Sickness Impact Profile exhibited the best qualities of the generic instruments in heart failure patients while the MLwHF was the disease specific measure which had the optimal performance. The authors recognised the limitations in quality of life questionnaires in general and recommended that generic and disease specific questionnaires be used in

combination to cover a wider range of domains in heart failure patients. (Berry, McMurray 1999)

The second review article was concerned with the ability of questionnaires to determine aspects of quality of life which are important to heart failure patients – to "take account of the patient perspective". (Dunderdale et al. 2005) The SF-36 was one of the generic instruments reviewed in addition to the Nottingham Health Profile (NHP) and the Sickness Impact Profile (SIP). The extensive use and validity of the SF-36 in various patient populations was noted as was its sensitivity to change and suitability for heart failure populations. All of the generic measures reviewed were recommended for use in conjunction with a disease specific measure in heart failure research. The authors commented on the lack of evidence to show that the most commonly used disease specific measures are patient centred. Although the measures reviewed, including the MLwHF, were all well validated, the authors did not make any direct comparisons or conclusions regarding the most appropriate tool for use. (Dunderdale et al. 2005)

A systematic review with meta-analyses did however directly compare disease specific questionnaires. They identified 421 full text peer reviewed articles of which 94 had data relating to the five most commonly used disease specific tools: the MLwHF, the CHFQ, the QLQ-SHF, the KCCQ and the LVD-36. Cronbach's alpha was high for all the measures on scales indicating physical domains. All questionnaires had moderate to strong association with the validity

criteria used: NYHA class, the six-minute walk test and the SF-36. The MLwHF was found to be the strongest disease specific measure when estimates from eight meta-analyses were pooled and this evidence would support its use as a first line disease specific measure in heart failure patients. (Garin et al. 2009)

Disease specific measures are more useful in measuring quality of life than generic tools in heart failure populations. (Ni et al. 2000, Bennett et al. 2002) Generic measures should not be used alone but may be combined with a disease specific instrument depending on the study objectives.

Measuring psychological impairment

Emotional disorders and psychological distress are common in heart failure patients and need to be considered when assessing quality of life. The generic and disease specific measures have emotional or mental components but the impact of psychological distress in heart failure patients may require the use of a specific tool. The Hospital Anxiety and Depression Scale (HADS) is one such example.

The (HADS) is a 14-point survey which was developed to screen for anxiety and depression among patients in non-psychiatric hospital clinics. (Zigmond, Snaith 1983) It consists of seven anxiety subscale questions and seven depression items. It has demonstrated reliability and validity in both primary and secondary care.(Bjelland et al. 2002) It is an adequate screening tool in primary care and compares favourably with the Mini International Neuropsychiatric Interview (MINI) (Bunevicius et al. 2007) and the Patient Health Questionnaire (PHQ-9) (Cameron et al. 2008) which are also used to screen for mental disorders in primary care. It has been used to successfully identify psychological distress in heart failure patients recruited from general practice. (Scherer et al. 2007)

Measuring quality of life in heart failure: conclusions

Quality of life is both subjective and multi-dimensional. It must be measured from the patient's perspective and information on various aspects of the patient's life is required for its adequate assessment. Questionnaires are a useful tool in measuring quality of life and may be generic or disease specific in nature. Generic instruments, such as the SF-12, aim to summarise health across various aspects of quality of life but when used to assess quality of life for patients with heart failure should be combined with another instrument due to their lack of sensitivity to change. The SF-12 and the MLwHF are well validated tools and have been tested for use heart failure patients. As quality of life in these patients is often affected by psychological distress, a tool such as the HADS may be used to complete a global quality of life assessment.

Chapter 4 - A study exploring quality of life and unmet needs of patients with heart failure in a General Practice population

Introduction

As highlighted in the literature review heart failure is a condition which results in considerable morbidity and mortality. (Davis, Hobbs & Lip 2000, Davis, Albert & Young 2005) The detrimental effect of heart failure on quality of life is well documented but there is a poor level of understanding of the impact of this disease on patients' daily lives.

Quality of life data in patients with heart failure have traditionally been obtained through clinical trials in secondary care. There is evidence that the patients who are enrolled in these trials are not representative of the heart failure patient population (Krumholz 1998, Masoudi et al. 2003) and do not reflect the patients seen in general practice.

The high incidence of cardiovascular disease and the increasing ageing population make heart failure likely to cause a considerable workload for general practice in the future. Following the introduction of the Quality and Outcomes Framework in general practice, heart failure registers have facilitated more

accurate identification of patients with this condition. This has facilitated the recruitment of patients with a confirmed diagnosis of heart failure for this study.

The principle aim of this piece of work is to gather information about quality of life and unmet needs of patients with heart failure in the Northern Ireland community. This information is not currently available and is necessary for improving the care and treatment in this patient group.

Aim of study

The aim of this study is to explore quality of life and unmet needs in heart failure patients in the Northern Ireland general practice population.

Study Objectives

- To examine differences in self reported quality of life between people in NYHA classes I and II and classes III and IV

- To explore if quality of life in heart failure patients is associated with disease, demographic and social factors

- To identify the unmet needs of patients' with severe heart failure (NYHA classes III and IV) in order to suggest improvements for their future care

Study Hypothesis

It is hypothesised that quality of life, as measured by the disease specific questionnaire, will be significantly reduced in patients with a higher NYHA class. Increasing age, lower social class, higher levels of co-morbidity and living alone would also be expected to be associated with a significant reduction in quality of life scores as measured by all three QOL instruments.

Study Methods

Study Design

The study had two distinct stages with a mixed method design. The design was chosen as it was felt to be the most appropriate to meet the study objectives (see page **67**). The first stage, a cross sectional postal questionnaire survey, involved gathering quality of life data from a wide range of heart failure patients throughout Northern Ireland. The second stage aimed to assess individual patient's perceived unmet needs using semi-structured interviews. A qualitative approach is particularly appropriate when assessing unmet needs as a patient's perception of need is highly variable and is difficult to assess using a standardised tool.

In the first stage quality of life data was obtained using three well validated questionnaires, the Minnesota Living with Heart Failure questionnaire (MLwHF), the Short Form-12 (SF-12), and the Hospital Anxiety and Depression scale (HADS). These were posted to heart failure patients identified from general practice heart failure registers. Quality of life scores were then analysed for significant differences depending on disease factors (NYHA class, co-morbid conditions), demographic factors (age, gender), and social factors (social class, marital status).

Purposive sampling was used to identify participants for stage 2 of the study from stage 1 respondents. A range of patients and potentially information rich cases were identified to be invited to participate in the semi-structure interviews.

Methods for stage 1

A sample of general practices in Northern Ireland was invited to participate in the study. The practices were randomly selected to be representative of Northern Ireland general practices in terms of list size and geographical location. Randomisation was used in the selection process to reduce selection bias.

The Department of Health Social Services and Public Safety list of QOF practices from 2007 to 2008 (Department of Health, Social Servies and Public Safety 2009) was used to stratify practices in terms of list size and board area and 10 practices were randomly select by the study statistician using random number tables. Initially stratification in terms of socioeconomic status was also considered in selection of practices, however given the small sample size (n=10) which was being drawn from the sample frame, it was not possible to stratify for a further variable. The number of practices chosen was based on the study sample size calculation shown below.

Sample size calculation

The sample size calculation was based on the primary research question and the primary outcome measure selected to address this question.

Primary research question

Is there a difference in self reported quality of life between patients in NYHA classes I and II and patients in NYHA classes III and IV?

Primary outcome measure

The primary outcome measure was the quality of life score as calculated by the Minnesota Living with Heart failure questionnaire. It was expected that a significant difference in quality of life scores would be demonstrated between patients in NYHA classes I and II and those in NYHA classes III and IV, using this primary outcome instrument. The sample size calculation was based on the likely size of the difference (in terms of mean and standard deviation scores) between these two groups using this quality of life measure.

Method of calculation

To compare the mean quality of life scores for each group (NYHA I-II and NYHA III-IV) the equation for comparative research studies was used. (Eng 2003)

The equation used can be expressed as follows:

$$N = \frac{4\sigma^2 (Z_{crit} + Z_{pwr})^2}{D^2}$$

Where:

N = sample size

σ = the standard deviation of each group (this was assumed to be equal for both groups, and the value used was obtained from a study which looked at discriminant properties of quality of life tools in heart failure.(Bennett et al. 2002)

Z_{crit} = 1.96 (Z value which corresponds to the 95% confidence levels)

Z_{pwr} = 1.282 (Z value which corresponds with a desired power of 0.90)

D = The minimum expected difference between the two means

Therefore using the standard values and those obtained from previous research:

$$N = \frac{4(27.24)^2 (1.96 + 1.282)^2}{20^2}$$

$$N = \frac{30565.45}{400}$$

$$N = 76.41$$

This equation does not take clustering effects into account. Therefore based on the assumption that the number of patients obtained from each GP practice would be approximately equal and using the sample size of 76, we estimated that approximately 8 patients would be obtained from each cluster.

When measuring subjective assessments of health-related quality of life we expect a range of factors to influence outcomes, however the GP practice is unlikely to play a part in this. As a result of this the intra-cluster correlation was expected to be low in this sample and a cluster correlation of 0.01 was chosen by the study statistician. This resulted in a design effect of 1.07, and an increased sample size of 82.

Therefore sample size allowing for clustering = 82

Recruitment of adequate sample size

An estimated response rate of thirty percent was used to predict the numbers needed to recruit.

$N_{recruit}/100 \times 30 = 82$

$N_{recruit} \times 3 = 820$

$N_{recruit} = 274$

The average practice heart failure prevalence in Northern Ireland is approximately 0.82%.(Department of Health, Social Services and Public Safety, Northern Ireland 2007) Using this average prevalence a sample it was estimated that to recruit 274 patients with heart failure approximately 10 practices would need to be recruited to the study.

Practice and Participant recruitment

The practices selected were sent the study information by post and asked to return the consent form if they wished to participate. The practices who did not respond were sent a reminder letter after 2 weeks. Practices which declined participation or those who did not respond to either invitation were replaced with a practice matched for list size and board area. A total of nine practices were

recruited within the time frame allocated for recruitment (December 2008 to April 2009).

When recruited, practices were asked to identify patients from their heart failure registers who met the study's inclusion criteria as below;

- Diagnosis of heart failure identified from the practice heart failure register.
- Age greater than 18 years
- Able to complete a questionnaire
- No cognitive dysfunction
- Able to consent to participation in the study
- English speaking

Patients under the age of 18 were excluded as the focus of the study was adult patients with heart failure. Due to restrictions on translated versions of the study questionnaires, those who did not speak English were also excluded.

Following identification of potential participants the practice then forwarded the study information to these patients. The information sent to the potential participants included: (**See Appendices);**

- The study patient information sheet detailing the background and aims of study

- A demographic questionnaire
- The Short-form 12 (SF-12)
- The Hospital Anxiety and Depression scale (HADS)
- The Minnesota Living with Heart Failure Questionnaire (MLwHF)
- A study consent form
- A stamped addressed envelope for return of the survey to the researcher

From the pilot work it was estimated that recruiting 10 practices would allow identification of adequate numbers of patients for this study. The sample size calculation was based on the likely effect size of the difference in quality of life scores between patients in NYHA classes I and II and those in classes III and IV using the MLwHF (See pages 71-73). A sample size of 82 participants was required to detect a significant difference at 90% power and 95% confidence. The response rate was estimated at 30% therefore approximately 274 patients would need to be sent the study information in order to get an adequate sample based on the pilot work.

In the first stage of the study quality of life data was collected using the three well validated quality of life questionnaires: the Minnesota Living with Heart Failure questionnaire (MLwHF), the Short Form 12 (SF-12) and the Hospital Anxiety and Depression scale (HADS). These questionnaires were chosen to cover a wide range of domains that were thought to contribute to quality of life. Both disease specific and generic quality of life instruments were included to

measure if variables affected disease specific quality of life and generic quality of life differently. As the study participants were being asked to complete three questionnaires the shorter SF-12 was chosen instead of the SF-36.

Questionnaires were returned to the researchers at the Department of General Practice, Queen's University Belfast. The participating practices were asked to provide anonymous data for all patients sent the study information so the characteristics of the responders and non-respondents could be analsysed for any significant differences. The anonymsed patient characteristics provided by the practices included age, gender, and postcode.

The postcodes of patients were used to calculate a multiple deprivation measure score.

"The Northern Ireland Multiple Deprivation Measure (NI MDM) is the official measure of spatial deprivation in Northern Ireland." (Northern Ireland Statistics and Research Agency 2008)

For the purposes of calculation of the NI MDM the geographical area of Northern Ireland is divided into 890 super output areas (SOA). Each SOA covers a population of approximately 1800 people and information from seven domains are used to determine the MDM score and rank of this pre-defined area. The domains included in the MDM equation are: Income deprivation, Employment deprivation, Health Deprivation and Disability, Education Skills and Training

deprivation, Proximity to Services deprivation, Living Environment deprivation, and Crime and Disorder. Each of these domains carries a specific weight and the NI MDM score is the combined sum of the weighted, exponentially transformed rank of the domain score. A deprived area will therefore have a low MDM score and a low MDM rank.

The postcode of each patient sent the study information was used to determine their corresponding SOA. The NI MDM score of each SOA was translated into a MDM score using tables provided by the Northern Ireland Statistics and Research Agency.

Data analysis

The data obtained from the postal questionnaire survey was entered into SPSS version 16 and this software package was used for analysis. The MLwHF and HADS questionnaires were scored manually and the SF-12 questionnaires were scored using the Health Outcomes Scoring package provided by the licensing authority. Analysis of data was performed in the Department of General Practice at Queen's University, Belfast with support from the study statistician.

The primary outcome measure used was the quality of life score as calculated from the MLwHF questionnaire. The mean MLwHF scores from patients in New York Heart Association (NYHA) groups I and II were compared with the scores of patients in NYHA class III and IV with an independent t-test. This process was

repeated for the secondary outcome measures. The mean scores obtained from the SF-12 PCS and the SF-12 MCS and the HADS in NYHA class I and II patients were compared with those obtained from patients in NYHA class III and IV.

The effect of demographic characteristics such as age, gender, co-morbidity, social class and marital status on quality of life scores was analysed for each questionnaire using multiple regression.

The variables such as co-morbidity and marital status were entered into SPSS as binary response variables. One of the assumptions of regression is that the independent variables within the model are not related. If variables within the model are related collinearity will exist. This can be problematic in small studies. When co-morbidity and marital status were entered into the regression model in the study the tolerance values for these variables approached 0.2 indicating significant collinearity. To rectify this one of the co-morbid categories and one of the marital status categories were removed from the model and the others were compared to the category which was omitted. Following this the tolerance values, which indicate the degree of collinearity, were much higher than 0.2. Variables were then removed from the model using backward elimination to leave only the significant variables. However due to the need to omit one of the co-morbid and marital status categories, it was not possible to remove individual categories. The significance of these collective group of categories was determined by examining the effect of removing all or none of the categories on

the R^2 value. The R^2 value indicates the degree of variation in the dependent variable which can be attributed to the independent variables. Therefore if the marital status categories were removed and the R^2 value decreased it indicated that marital status had a confounding effect as it contributes to the variation in the dependent variable i.e. the quality of life score. All marital status categories would be replaced in the model even if some of the individual categories were not significant.

Bivariate analysis was used to determine the significance of individual co-morbid conditions such as lung disease, arthritis, and angina when co-morbid was found to be confounding.

The characteristics of the respondent s and non-respondents were compared using Chi-square for gender, the Mann Whitney U test for MDM score and the independent t-test for age.

Methods for stage 2

The second stage of the study aimed to identify patients' unmet needs through semi-structured interviews. Purposive sampling was used and variables such as age, gender, geographical location, heart failure severity, and quality of life scores were considered in selection of participants. The aim was to identify a wide range of patients and potentially information rich cases. These patients were expected to have a wide range of unmet needs and therefore more likely to highlight areas for improvement of heart failure care. The general practitioners were asked to identify patients with a history of violent behaviour as these patients were not selected for interview in order to minimise any risk to the researcher. Patients were contacted by telephone to inform them of selection for interview and to confirm consent for participation. Initially a purposive sample of approximately 10 participants was selected for participation in the second stage of the study. However due to time limitations and a lack of patients with severe heart failure consenting to interview, a total of 3 patients were interviewed.

A semi-structured interview format was used and interviews were conducted in the home of each patient. This format allowed some loose structure to focus the discussion while using open-ended questions encouraged patient directed responses. The interview questions were constructed considering the purpose of the research, results from the existing literature, and topics of interest to the researcher. The interviews were generally patient directed. However questions were constructed to ensure that the interview covered important areas. An

inductive approach was used throughout the interviews. All interviews were conducted by the lead researcher (MM) and were recorded using a digital recorder. The length of each interview was directed by the patient. The set questions included in the semi-structured interviews are included in appendix 12.

Interviews were conducted during May 2009. The audio files were transcribed by researcher and the transcripts were analysed using a framework for thematic analysis. Due to the limitation in the number of interviews data saturation was not achieved in the qualitative interviews and as are result these results may only be used to inform the qualitative data as in isolation they lack rigour.

Ethical considerations of the study

Confidentiality of participant data

Patients were given a unique study code at recruitment. This code appeared on each questionnaire so that responders were able to be identified. Only anonymous data was removed from the practice. The names, personal details and their corresponding codes were stored separately from the study data in a password protected file on a university computer.

Interviews in medical research pose a risk of disclosure of important information. This was discussed by the research team prior to data collection. If a patient made a clinical disclosure which may have required action it was agreed that the researcher would encourage the patient to go to their own GP or ask the patient's permission to do so on their behalf. As a medical practitioner, under the duties of a doctor and also as a researcher practising ethically it would not be appropriate to break the confidentiality of the interview. In the event of a disclosure which suggested that the patient was at risk, for example suicidal intent, or that not taking action would put others at risk of significant harm, the case would be discussed within the research team and in the event of necessity to break confidentiality, the patient would be informed prior to proceeding.

Non-maleficence

This study offered no direct benefit to the participants. The sensitive and personal nature of quality of life issues and unmet needs were recognised by the research team.

The Short Form-12 includes questions about limitations in lifestyle which may challenge patients to consider restrictions to their activities of daily living. Some participants may have found these limitations in their lives upsetting. The Minnesota Living with Heart Failure questionnaire includes a question on limitation of sexual activities which is an area some patients may have found embarrassing to discuss.

The term 'heart trouble' was used in the study information provided to patients as the researchers felt some patients may not have been familiar with the term heart failure and may have found it distressing.

During the interview process participants may have had difficulty discussing their unmet needs however as the interviews were patient directed it was felt that it was unlikely that patients would initiate discussion which would make them uneasy.

Autonomy

The patient information sheet for the study states that no person was under obligation to participate and that their medical care will be unaffected by a decision not to participate. Non-respondents were not contacted by the research team or the practice at any stage.

Ethical approval

An ethical proposal for this study was accepted by the Northern Ireland Committee of the National Research Ethics Service. The ethics reference number for the study was 08/NIR02/93.

Chapter 5 – Study Results

Practice characteristics

Nine practices from all health boards in Northern Ireland participated in the study. The four health boards in Northern Ireland in the years 2007/2008 were the Northern, Eastern, Southern and Western Health Boards. The practices included in the study are listed below with their corresponding board area and practice list size in the year ending 2007/2008. The average list size of the study practices was 4,821 compared to the Northern Ireland average list size of 5,164 for the same time period. Three of the practices selected were in the Eastern Board area, with two practices selected from each of the other board areas. The Eastern board covers the city of Belfast which is the area of highest population density in Northern Ireland. To gain a representative sample of practices more practices were invited from the Eastern Board area. The average practice list size for Northern Ireland in 2008 was 5,164.

Practice study number	Practice Board Area	Practice List size
1	Western	3,545
2	Eastern	6,735
3	Northern	3,304
4	Eastern	7,122
5	Western	6,718
6	Eastern	2,144
7	Northern	5,844
8	Southern	2,869
9	Southern	5,109

Table 3

Characteristics of study practices

Participant characteristics

From the 43,390 patients registered in the nine practices selected, 297 (0.68%) meet the study criteria and were invited to participate. Of the 297 patients invited to participate 90 replied giving an overall study response rate of 30.3%.

The study population is described in Table 4. The mean age of participants was 73 years and the majority of participants were male (56.7%). The most common NYHA classes were II and III, most patients were married or lived with their partner and over 77% of participants had two or more co-morbid conditions. The most commonly reported co-morbid conditions were arthritis (51%), hearing/visual impairment (39%), angina (34%), lung disease (32%), diabetes and gastrointestinal disease (26%).

Gender n (%)	
Male	51 (56.7)
Female	39 (43.3)
Age	
Minimum	40
Maximum	94
Mean	73

NYHA Class n (%)	
Class I	13 (14.4)
Class II	33 (36.7)
Class III	24 (26.7)
Class IV	20 (22.2)
MDM rank	
Lowest MDM rank	11
Highest MDM rank	883
Mean MDM rank	459
Marital status n (%)	
Single	9 (10)
Married/Live with partner	48 (53.3)
Widowed	24 (26.7)
Divorced/Separated	9 (10)
Co-morbidity n (%)	
No co-morbidity	7 (7.8)
1 condition	13 (14.4)
2 conditions	21 (23.3)
3 conditions	22 (24.4)
4 or more conditions	27 (30)

Table 4 Study population characteristics (N=90)

	Number of participants with condition (n)	% of participants with condition
Asthma	31	34.4
Kidney	14	15.6
Arthritis	46	51.1
Blood disorder	15	16.7
Asthma	8	8.9
Lung disease	29	32.2
Diabetes	23	25.6
Hearing/Visual impairment	35	38.9
Cancer	6	6.7
Stroke/ Brain condition	7	7.8
Mental Health	4	4.4
Gastrointestinal	23	25.6
Other	5	5.7

Table 5

Descriptive statistics of individual co-morbid conditions reported by study participants

Respondents and non-respondents

There was no significant difference between the gender of the respondents and the non respondents (Chi square = 1.2, p = 0.274) despite slightly more females being invited and more males responding (see Figure 6). The mean age of the respondents was 73 years while the non-respondents had a mean age of 73.3 years. No significant difference was found between the groups (t = 0.219, p = 0.827). The respondents and non respondent also did not differ in terms of MDM score (U = 8721.5, p = 0.383)

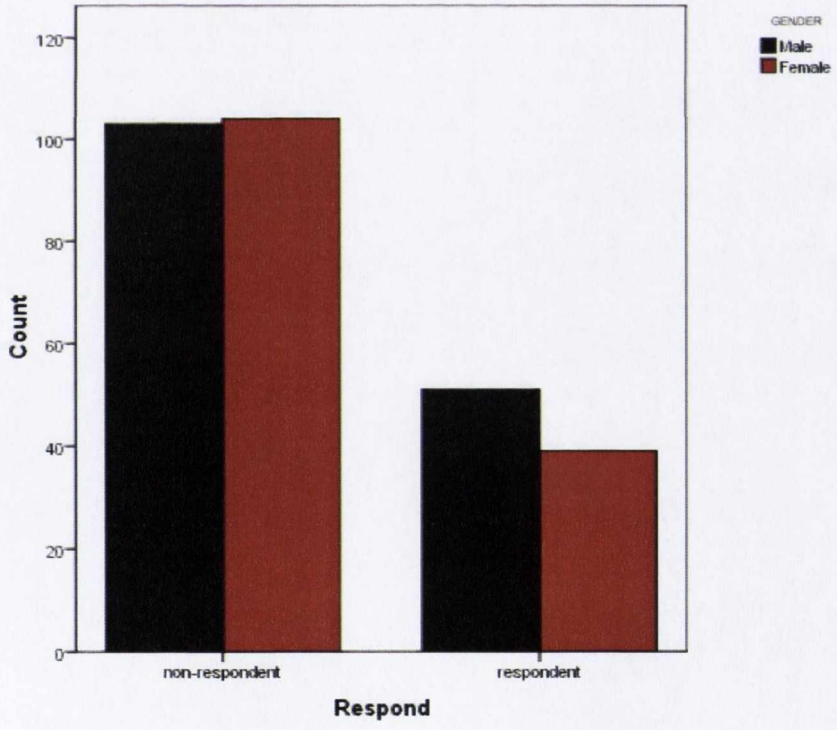


Figure 6

Bar chart showing frequency of male and female respondents and non-respondents

The Minnesota Living with Heart Failure Questionnaire (MLwHF)

A total of 87 (29.2%) valid MLwHF questionnaires were returned, 3 of the study participants did not complete the questionnaire. Some of the participants did not complete the question regarding the effect of heart failure on their ability to work as they were retired (See MLwHF, Appendix 10). A zero score was allocated in these cases.

The histogram below (Figure 7) shows that the MLwHF scores followed a near normal distribution. The total MLwHF scores ranged from 0 to 90. Higher numerical scores on the MLwHF correspond with poorer quality of life. The high frequency of lower MLwHF scores illustrated in Figure 7 could be due to response bias. Patients with less severe disease and better quality of life may have been more likely to respond leading to the positive skew in the results. However as the sample size is greater than 30 the normality assumptions for the statistical methods used to analyse these results can be relaxed.

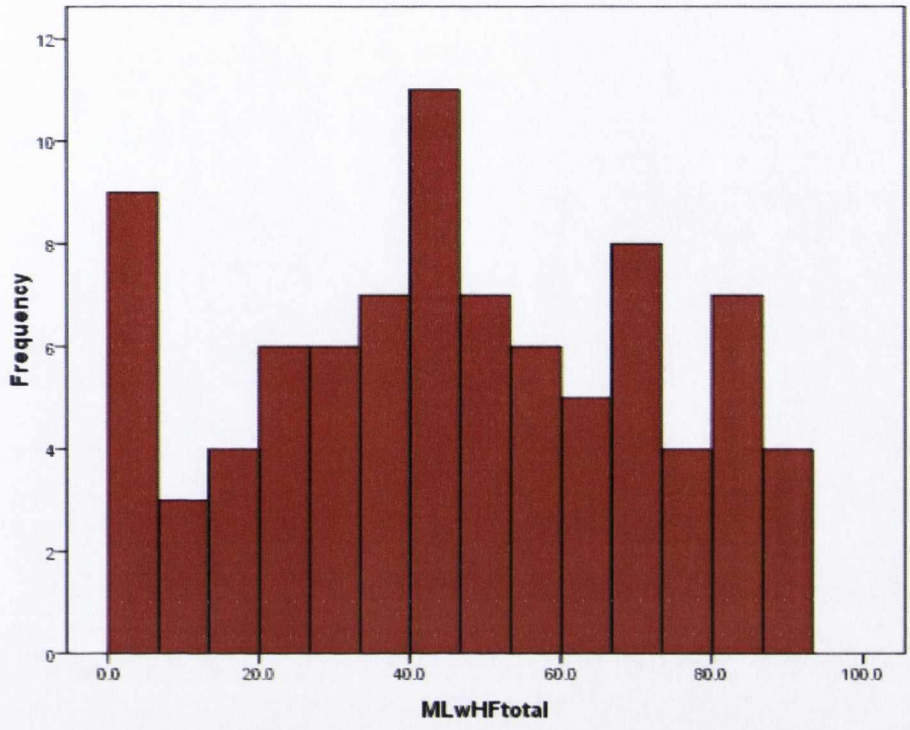


Figure 7 Histogram showing the distribution of total MLwHF scores

Disease severity

Patients in NYHA class I and II (n=45) had a mean MLwHF score of 32 with a standard deviation of 3.3. Patients in NYHA class III and IV (n=42) had a mean MLwHF score of 60 and a standard deviation of 3.3 also. There was a highly significant difference in mean total MLwHF scores between these two groups ($p<0.001$).

To check for the confounding effect of disease, demographic and social factors on the total MLwHF score a regression analysis was performed. Disease, demographic and social factors were responsible for 55% of the variation in

MLwHF total scores. The variables found to contribute to the model included NYHA class, age, co-morbidity and marital status. Although NYHA class was the only variable which had a significant p value (<0.001) in the regression model, having no co-morbid conditions (p=0.07) and being single (p=0.06) approached significance. Removing the other variables resulted in a decrease in the R square value indicating that although the p value for these variables were not significant, the variables contributed to the variation in MLwHF total scores.

Marital Status

Patients who were single had lower MLwHF scores than those who were married while those who were widowed or separated had higher scores than those who were married (see Figure 8).

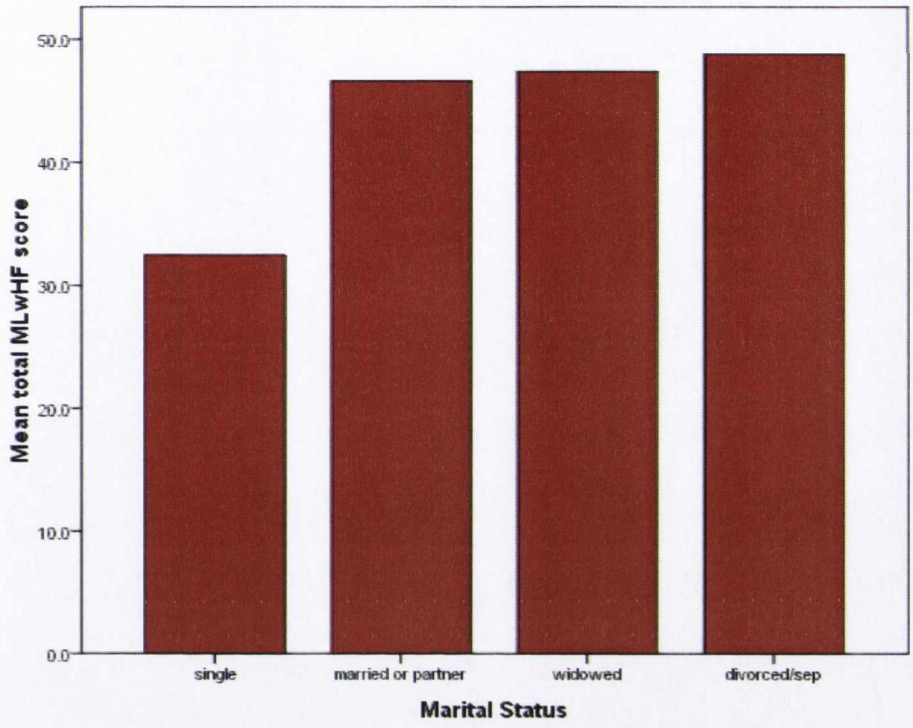


Figure 8 Bar chart showing relationship between marital status and the mean total MLwHF score

Co-morbidity

Co-morbidity is a confounding factor in quality of life as measured by the MLwHF, when other independent variables are held constant. Figure 9 illustrates the trend in mean total MLwHF scores at varying levels of co-morbidity. Those who have 2 or less co-morbid conditions have lower scores than those who have 4 or more co-morbid conditions.

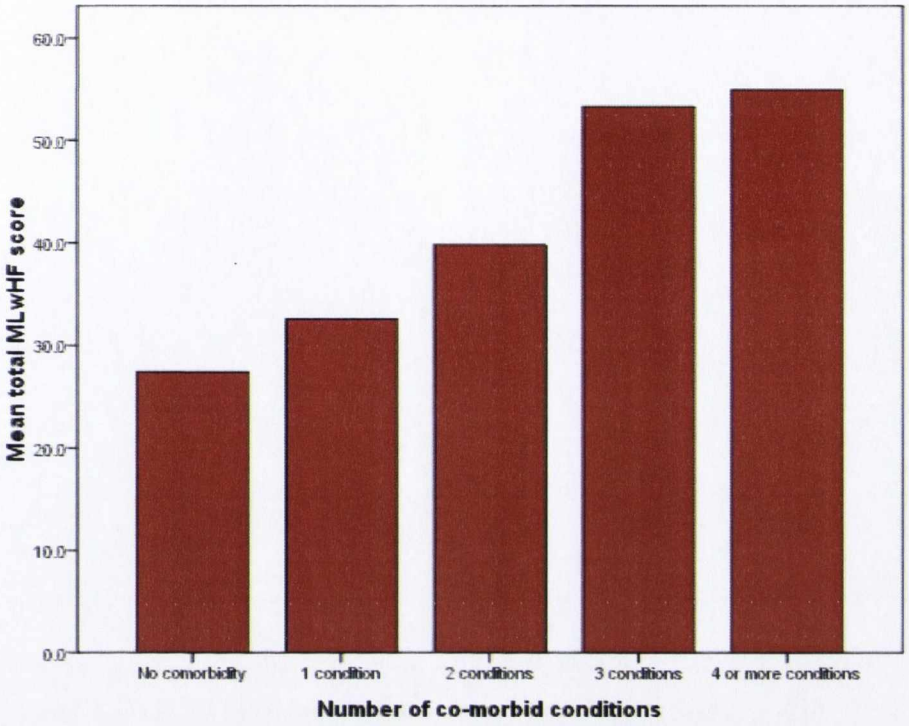


Figure 9

Bar chart showing the trend in mean total MLwHF score at various levels of co-morbidity

As co-morbidity was identified as a factor which contributed to total MLwHF score, individual co-morbid conditions were entered into a bivariate analysis to look for significant associations. A statistically significant correlation was found between MLwHF total score and having arthritis (p=0.02), blood disorders (p=0.03), mental health conditions (p=0.02), and gastrointestinal disease (p=0.05).

MLwHF Physical and Emotional Dimensions

Quality of life, as measure by the MLwHF physical and emotional health dimensions is also affected by NYHA class.

In the physical dimension patients in NYHA class I and II (n=45) had a mean score of 17 with a standard deviation of 1.7 while those in NYHA class III and IV had a mean score of 30 with a standard deviation of 1.3. A highly significant difference was found between these two groups ($p<0.001$).

The emotional dimension score was also affected by patients self-reported heart failure severity. Patients in NYHA classes I and II had a mean emotional dimension score of 7.1 with a standard deviation of 6.8 while those in groups NYHA classes III and IV had a mean score of 14 with a standard deviation of 8.3. As with the physical dimension, a significant difference was noted between these two patient groups ($p<0.001$).

Conclusion of MLwHF results

Disease specific quality of life in patients with heart failure in the Northern Ireland general practice population is affected by disease severity. The disease severity, as measured by the NYHA functional classification has an impact on both physical and emotional dimensions of quality of life. Patient factors also contribute to disease specific quality of life as measured by the MLwHF. In particular, age, level of co-morbididity, and marital status contributed to the variation in MLwHF scores adjusted for other factors. Patients with heart failure have a wide range of individual co-morbid conditions. Those which have been shown to be associated with disease specific quality of life include arthritis, blood disorders, gastrointestinal disease and psychiatric conditions.

The Short-Form 12 results

The output from the completed SF-12 questionnaires (n=89) was entered into the software package producing a physical (PCS) and mental (MCS) component summary score. The results of the PCS and MCS were analysed separately. Higher numerical scores on these scales indicate better quality of life.

The physical component summary (PCS) results

Participant scores on the PCS ranged from 11.6 to 59.7 with a mean participant PCS of 29.7. The histogram in Figure 10 illustrates the spread of PCS scores in all participants. In the study sample 90% of participants were below the population norm used for the PCS, 6% scored at the general population norm and only 4% were above the general population norm (See aggregate report form SF-12 scoring software, Appendix 13)

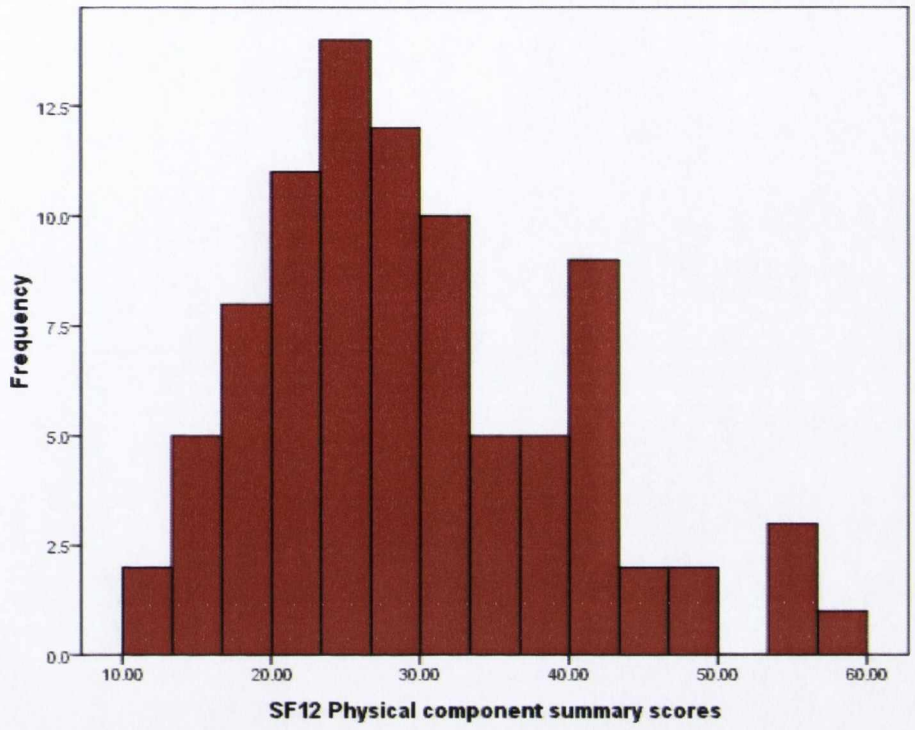


Figure 10

Histogram illustrating SF-12 PCS scores in all participants

Disease severity

Patients in NYHA class I and II had a mean PCS score of 34.1 with a standard deviation of 11.6 while those in NYHA class III and IV had a mean score of 24.9 with a standard deviation of 6.4. There was a significant difference in PCS scores between these two groups ($p<0.001$).

The independent variables were responsible for 49% of the variation in PCS scores. The factors which contributed in the regression model were NYHA class ($p<0.001$), gender ($p=0.01$) and co-morbidity. Having no co-morbid conditions was a significant confounder ($p=0.04$). Although the other categories of co-morbidity did not have significant p values in the model, they could not be removed due to the significant effect of the no co-morbidity category. If all co-morbid categories were removed the R square value decreased indicating that this variable contributed to the variation in PCS scores.

Gender

Gender was a significant confounder. Females had lower scores on the PCS than males indicating that they had a poorer quality of life (See Figure 11).

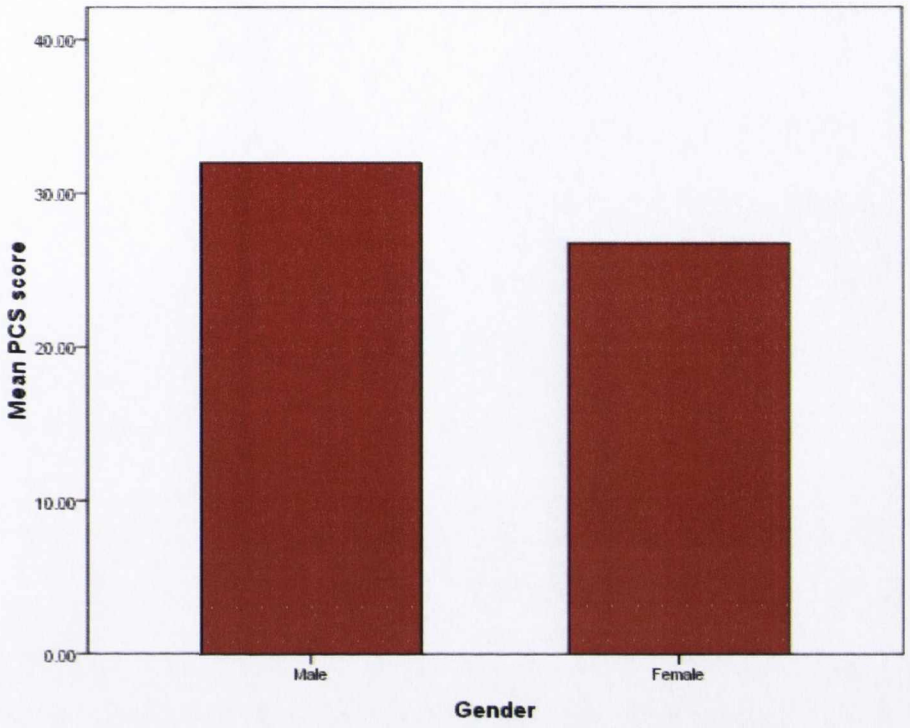


Figure 11

Mean PCS scores in males and females

Co-morbidity

Patients with 1 or less co-morbid conditions had better quality of life scores on the PCS than those with 4 or more co-morbid conditions. The trend in PCS with varying levels of co-morbidity is illustrated in Figure 12. In contrast to the MLwHF scores, PCS scores decrease with increasing level of co-morbidity. However both show that as co-morbidity increases, quality of life decreases.

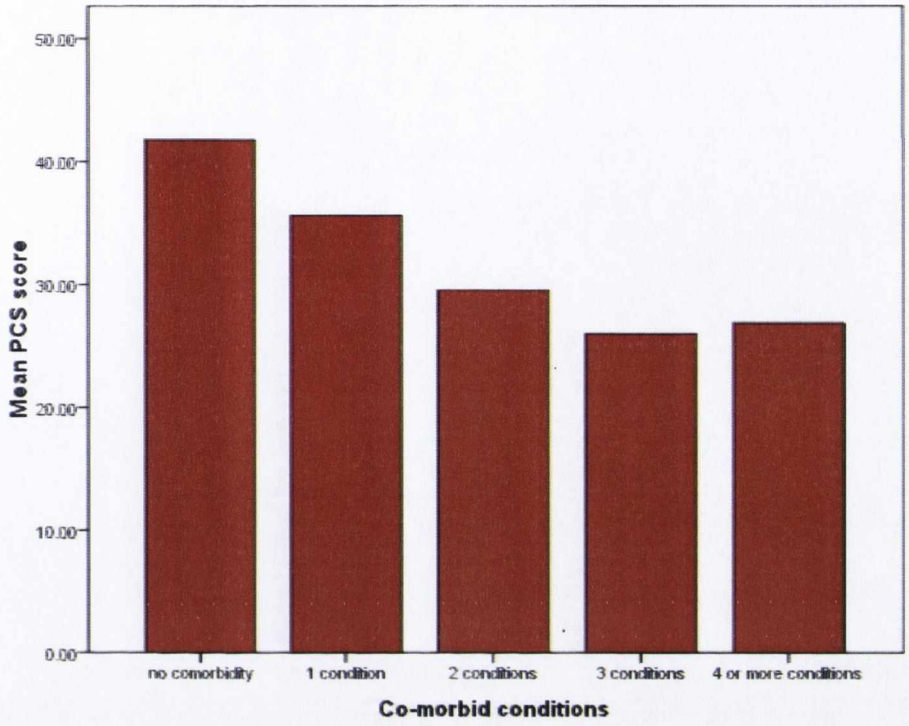


Figure 12

Relationship between number of co-morbid conditions and PCS score.

As with the MLwHF, arthritis was significantly associated with PCS scores, using bivariate analysis (p=0.005). The other co-morbid conditions which showed a significant correlation with the PCS score were angina (p=0.05) and hearing or visual impairment (p=0.03). Each of these conditions had a negative correlation coefficient indicating that the presence of the condition decreased quality of life score as measured by the SF-12 PCS.

The Mental component summary scale (MCS)

The MCS scores from all valid SF-12 questionnaires returned (n=89) ranged from 16.6 to 65.7. The scores on the MCS were higher than those on the PCS reflected in the MCS mean of 45.9 compared to the PCS mean of 29.7. Higher scores on the SF-12 components indicate a better quality of life, suggesting that the patients in this study had better quality of mental compared to physical health. The histogram in Figure 13 illustrates the distribution of MCS scores in the study population. When the MCS scores of the study population are compared to population norms using the SF-12 software, 49% of the study participants were below the population norm, 20% scored at the population norm and 31% were above the population norm (See aggregate report from SF-12 scoring software, Appendix 13)

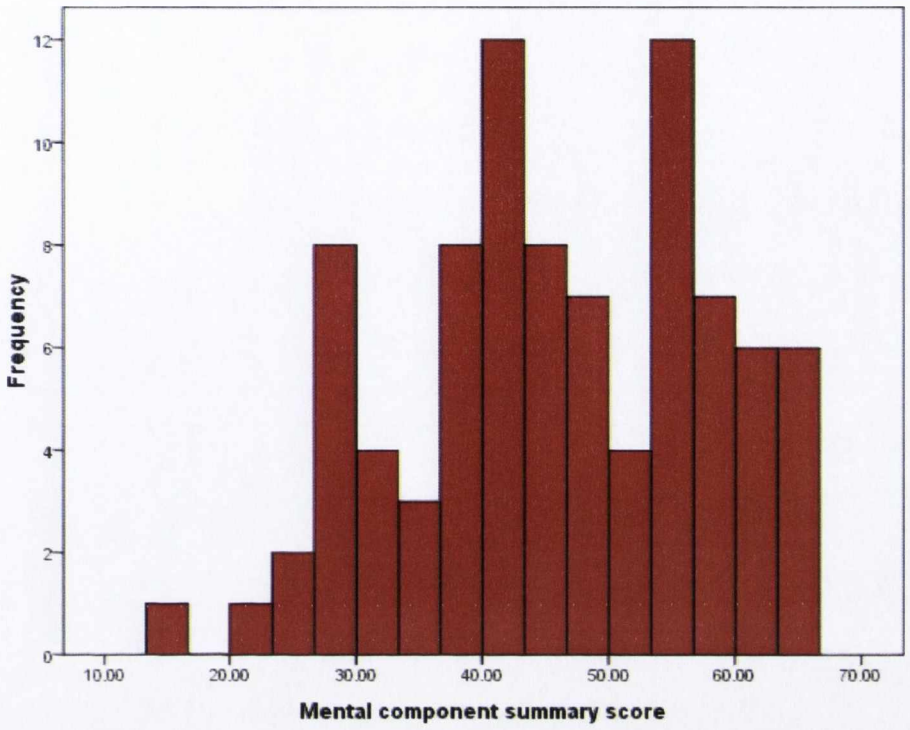


Figure 13

Histogram illustrating SF-12 MCS scores in all participants

Disease severity

Patients in NYHA class I and II (n=46) had a mean MCS score of 50.4 with a standard deviation of 10.8 while those in NYHA class III and IV (n=43) had a mean MCS score of 41.3 with a standard deviation of 11.1. There was a significant difference in MCS scores between classes I and II and II and IV ($p<0.001$).

The independent variables which contributed to the 36% of variation in MCS scores were age, gender, NYHA class and marital status. Co-morbidity was not a significant variable in the regression model for MCS scores. NYHA class ($p<0.001$), age ($p=0.04$) and being divorced or separated ($p=0.05$) all reached statistical significance in the model. The other categories of marital status were therefore unable to be removed from the model despite not being significant individually. Gender approached statistical significance ($p=0.08$) but when this variable was removed from the model the R square value decreased, reducing the degree of variation in MCS scores explained by the independent variables. Therefore gender contributes to the model despite not having a significant p value.

Age

Age was a significant confounding variable in the MCS regression model. When all other independent variables are held constant a one year increase in age is associated with a 0.24 increase in SF-12 MCS score. This indicates that older patients have a slightly better quality of life, as measured by the MCS, than younger patients.

Marital status

The multiple regression model also indicated that marital status contributes to variation of MCS scores. Being divorced or separated had the most significant

effect on scores, with these patients having significantly lower scores than those who were married or lived with a partner. The bar chart in Figure 14 illustrates the relationship between marital status and SF-12 MCS score. Patients who were single had the highest average MCS scores of the marital groups, as was found with the MLwHF.

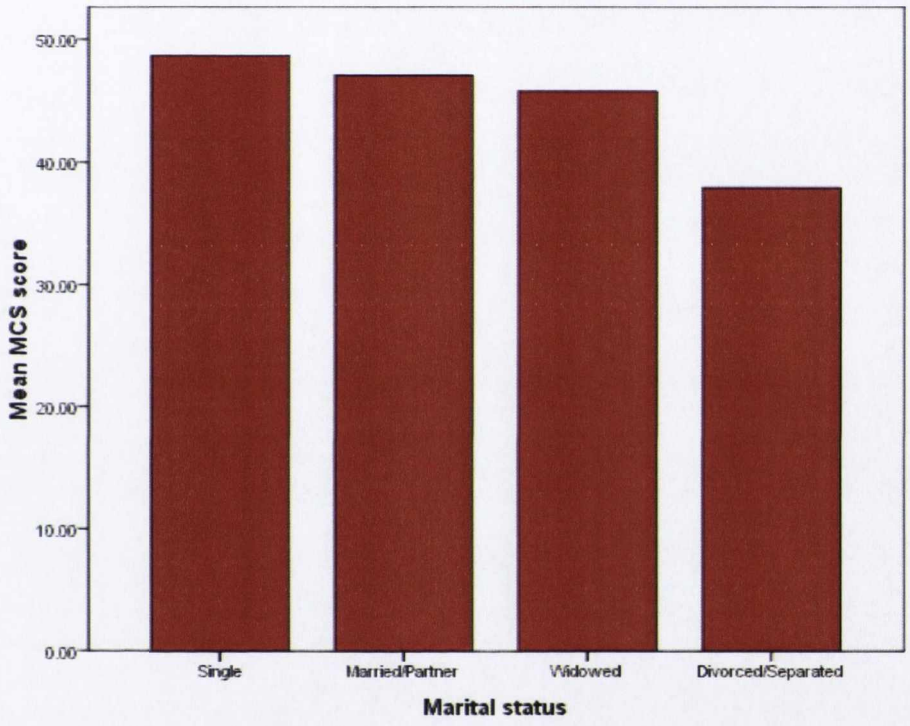


Figure 14

Relationship between marital status and MCS score

Gender

Females have lower scores on the MCS in addition to the PCS. The mean MCS score for females was 44.5 while males had an average score of 47.1. Females with heart failure therefore have an overall poorer quality of life than males when a generic measure is used.

Conclusion of SF-12 results

The physical and mental components of quality of life using a generic tool are affected by gender and disease severity (See Figure 15 and 16). Females and patients with more severe disease have a poorer quality of life. Physical quality of life is influenced by disease, demographic and social factors to a greater extent than mental quality of life. Co-morbidity has a detrimental effect on physical quality of life in patients with heart failure and conditions particularly associated with impaired physical quality of life include arthritis, angina and impairments of vision and hearing. Co-morbidity however does not affect the mental component of quality of life in this group of patients. Mental health is better in older patients with heart failure and in those who are married or live with a partner. Single patients also have good scores on the mental component scores while those who are divorced or separated have the poorest mental health scores compared to those of other marital states.

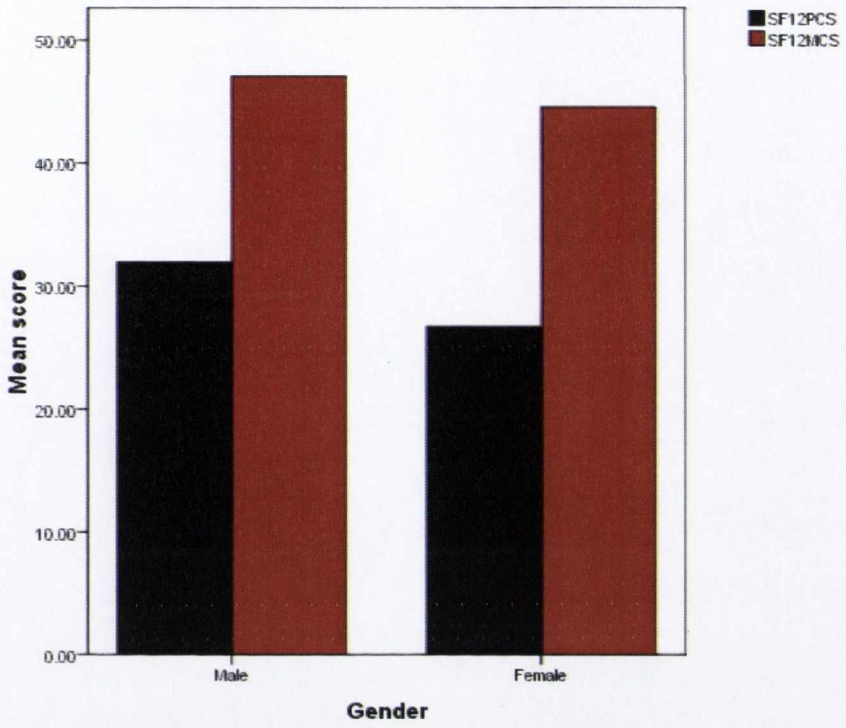


Figure 15

SF-12 PCS and MCS scores in males and females

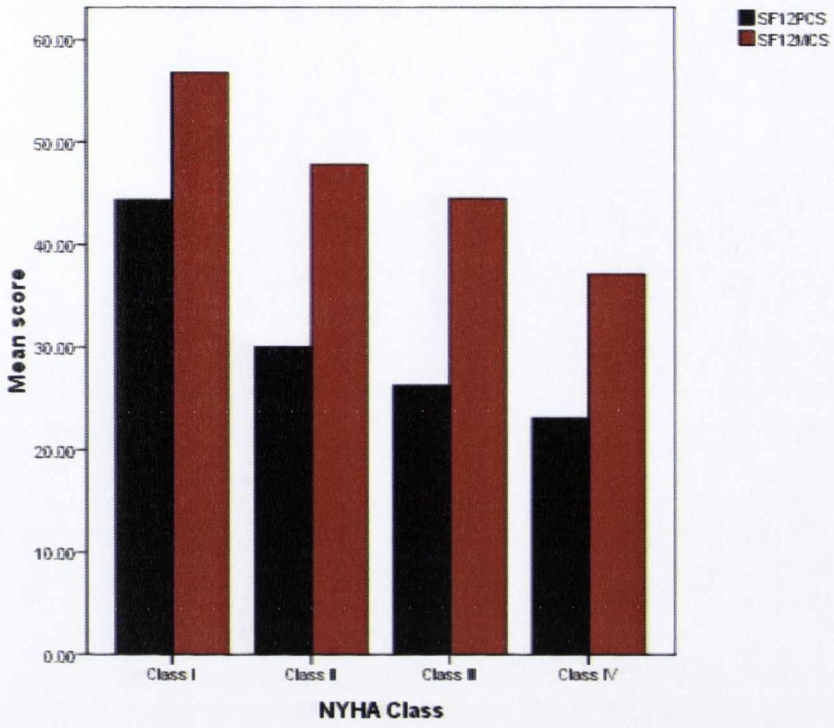


Figure 16

SF-12 MCS and PCS scores in patients of varying NYHA class

The Hospital and Anxiety Scale (HADS) results

From the completed HADS questionnaires (n=83) a total score was obtained by totalling the individual responses. This total score gives an overall impression of the level of psychological well-being in the study participants. The HADS scores ranged from 2 to 34. The maximum score attainable in the HADS questionnaire is 42. This corresponds to high levels of psychological distress. The mean HADS score in the study population was 14.6.

Disease severity

Patients in NYHA class I and II (n=42) had a mean HADS score of 11.1 with a standard deviation of 6.8 while those in NYHA class III and IV had a mean HADS score of 18.2 with a standard deviation of 7.5. There was a significant difference ($p<0.001$) in the level of psychological wellbeing, as measured by the HADS between these two groups of patients. As disease severity increased, psychological wellbeing in patients with heart failure decreased.

The independent variables which contributed to 48% of the variation in HADS scores were age, gender, NYHA class, level of co-morbidity and marital status. MDM score was the only variable which did not contribute to the regression model. The variables which were found to be significant confounders were age ($p=0.007$), NYHA class ($p<0.001$), and having no co-morbid conditions ($p=0.05$). Gender approached significance (0.07) but removing it from the model resulted

in a reduction in the R square value indicating that it contributed to the variation in HADS scores. In the same way the categories of marital status were not significant in their own right but removing them from the model also resulted in a reduction in the R square value.

Age

Age was highly significant in the regression model. It had an inverse relationship with the HADS scores. With other independent variables held constant, a one year increase in age resulted in a reduction in the HADS score by 0.22 indicating that in patients with increasing age HADS scores were lower. Therefore older patients with heart failure have better levels of psychological wellbeing than younger patients.

Co-morbidity

The degree of co-morbidity affects psychological wellbeing in patients with heart failure (see Figure 17). Patients with 2 or less co-morbid conditions have better psychological wellbeing than those with 4 or more conditions. Patients with no co-morbid conditions have significantly less impairment in psychological wellbeing than those with any co-morbidity.

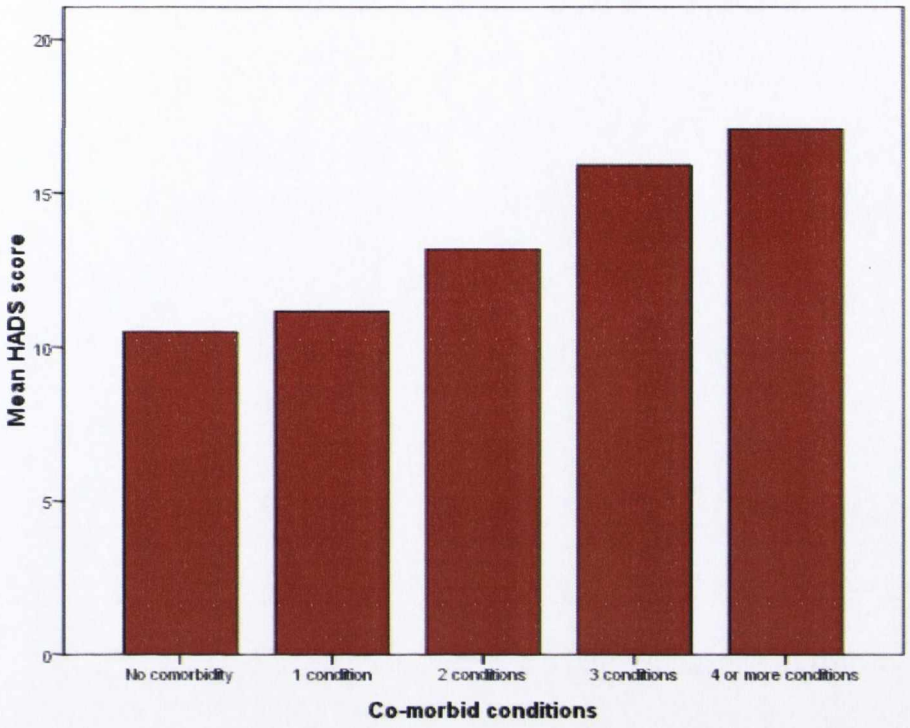


Figure 17

HADS scores at varying levels of co-morbidity

The individual conditions which demonstrated a significant association with the total HADS score were blood disorders (p=0.003), gastrointestinal disease (p=0.008), and psychiatric illness (p=0.03). These conditions all produced a positive Peason's correlation coefficient with the HADS suggesting that higher HADS scores were found in patients who identified these as co-morbidities.

Marital Status

Single patients had the lowest HADS scores and those who were divorced or separated had the highest HADS scores. In the non-single patients the presence of an ongoing relationship protected against psychological distress. Patients who were married or had a partner had lower HADS scores than those who were divorced, separated or widowed. This is illustrated in Figure 18.

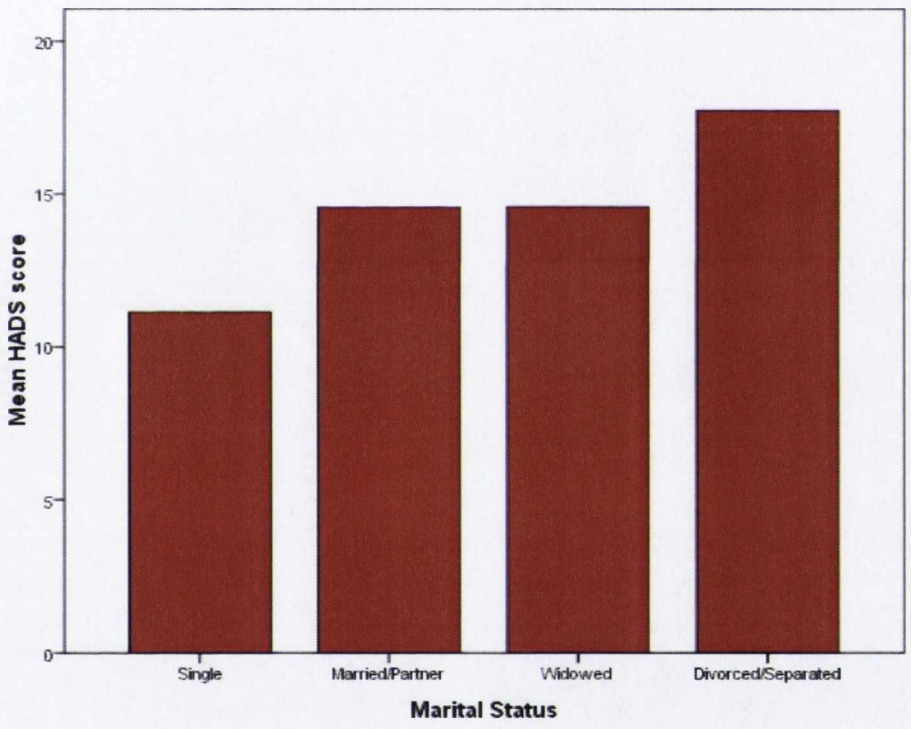


Figure 18

Relationship between marital status and HADS score

Gender

Female patients had higher scores on the HADS than male patients. Female patients with heart failure appear to have poorer levels of psychological wellbeing, a finding corroborated by females having poorer quality of life on the SF-12 MCS.

Conclusion of HADS results

Psychological wellbeing in patients with heart failure is affected by disease factors such as disease severity and level of co-morbidity, demographic factors such as age and gender and social factors such as marital status. Better psychological health is found in older patients and men with heart failure. Single patients have better HADS scores than those who are married or live with a partner while those who are divorced or separated have the poorest scores and therefore the highest levels of psychological distress. The presence of co-morbid conditions impairs psychological wellbeing in heart failure patients. Blood disorders, gastrointestinal disease and psychiatric illness were identified as having significant association with psychological wellbeing in patients with concurrent heart failure.

Results of stage 2 – Patient interviews

The reduced amount of data in the second stage limits its use as a qualitative study in isolation, however the three interviews uncovered certain themes which inform the quantitative data. The three participants were all in self-reported NYHA class 4 and were selected from the small number of stage 1 respondents who consented to interview. Interview transcripts were searched for recurring themes.

The central theme in all three interviews was reduced quality of life as a result of functional limitation.

"....you don't have a quality of life, so you don't."

(Participant 1)

Patients viewed heart failure primarily in terms of the impact it had on their daily functioning.

"Simple things like showering. I showered every morning and now I can't. When I do (my partner) has to dry me because I don't have the energy to dry myself. I've got to depend so much."

(Participant 1)

The ability to do most things was affected by heart failure and several references were made to how current abilities to perform daily tasks compared to the past. The following quote is from a 54 year old gentleman who developed heart failure after a myocardial infarction while on a weekend away with his partner. He refers to his activities prior to developing heart failure and how the person he was before didn't come home after that day.

"I was a maintenance electrician, very active. I was working up to six days a week. We went away for that weekend and I didn't make it home."
(Participant 1)

The distinction between the patient's functional abilities compared to their peers was also recognised.

"....even things that normally a woman of my age would just take for granted, you have to think about and I do everything very slowly."
(Participant 2)

Functional limitations in heart failure were viewed as a consequence of the physical and psychological impact of disease on patients' lives. The physical symptoms identified included most commonly tiredness, breathlessness and oedema.

"I just can't do anything now...that's basically what it is. It stops me doing anything at all."

(Participant 3)

"I get short of breath very quickly now....I would be tired all the time. Sometimes I feel as if I am tired inside, I feel weary inside."

(Participant 2)

"Whole life turned around. Can't work, can barely walk at times. I get a lot of fluid swelling in the stomach so I have to go in and get tapped every three weeks. It affects the breathing too."

(Participant 1)

Psychological consequences included the effect of heart failure on concentration, memory and mood.

"....my memory is not that great now."

(Participant 2)

"I just can't concentrate...I used to read but the concentration is not there."

(Participant 1)

"He gets very, very depressed because he can't get out."

(Partner of participant 1)

Functional limitations led to a loss of independence and a dependence on family, especially partners. The importance of personal relationships in dealing with the effect of heart failure on life restrictions and quality of life was recognised.

"....it takes somebody with you. I'm lucky to have that."

(Participant 1)

However the impact of heart failure on relationships and the subsequent feelings of guilt because of this were recurrent themes.

"....my husband has been held back in that....sometimes I can sort of think back and say to myself I'm sure although we are 46 years married, it hasn't been much of a married life for him."

(Participant 2)

Methods of improving independence were viewed as very important. All three patients recognised access to personal transport and mobility aids as vital in maintaining some independence.

"I got the (mobility) scooter and I was able to get around again. I was able to go round the shopping centres with (my partner)....I wouldn't be without it now."

(Participant 1)

"It is a mobility car and it's a blessing....if we want to go out somewhere it will give me the independence to do that."

(Participant 2)

Loss of traditional roles and sense of self, inability to work, needing help with activities of daily living and house hold chores as well as the impact on leisure and travel were other consequences of increasing functional limitation.

"The mood gets very down (when my partners son does things in the house) because I will go, I should have been able to do that."

(Participant 1)

"That's a photo of me two years ago before I had the heart attack. There is times I don't recognise myself."

(Participant 1)

Hospital and community medical care was described as generally satisfactory but resources and at times social support were lacking. Input from heart failure nurses was felt to be integral in disease management and in helping patients cope with heart failure.

"They (the heart failure nurses) are very good. They really are...they come round and if I have any questions they will explain it to you and come back again. If they don't know they will find out and they will ring you back. They are brilliant."

(Participant 1)

"I have her (the heart failure nurse) phone number and she would say now if you need me just phone. That's a useful service....I really need it. I think it's important."

(Participant 2)

Despite the satisfaction with the heart failure nurse service patients did find hospital care at times led to feelings of depersonalisation.

"They (the doctors) just won't listen to you. You are not a person, so you are not. You are a number. The first thing they check is your wrist. You are a number and a piece of meat."

(Participant 1)

The need for greater levels of social support and financial support were recognised however the greatest unmet need identified was the need for better communication from healthcare professionals.

"I think most times you are the last to know....the consultant came round, didn't examine me, changed a tablet....and walked away."

(Participant 1)

"....we don't seem, to be getting any answers....there is the odd doctor that right away you know you wouldn't want to ask them things."

(Participant 2)

"To be honest with you I am not sure about the heart failure. It was all new to me and I didn't know one thing from another."

(Participant 3)

Adequate communication regarding prognosis was often lacking and patients expressed their fears for the future. One participant was attending a hospice and recognised the benefits of this care model, despite his initial reservations to accept palliative care input.

"It just seemed the beginning of the end but Marie Curie have been very good...Everyone thinks the hospice is just for cancer, which we did too. It's not."

(Participant 1)

"I look forward and I can only see things getting worse for me."

(Participant 2)

"They both have lost their mum and keep wondering when I am going to go. They don't come out and say it but I know they think it."

(Participant 3)

However despite the difficulties these patients face in dealing with the functional limitations, poor quality of life and daily challenges of living with heart failure,

"...you have good days as well." (Participant 1)

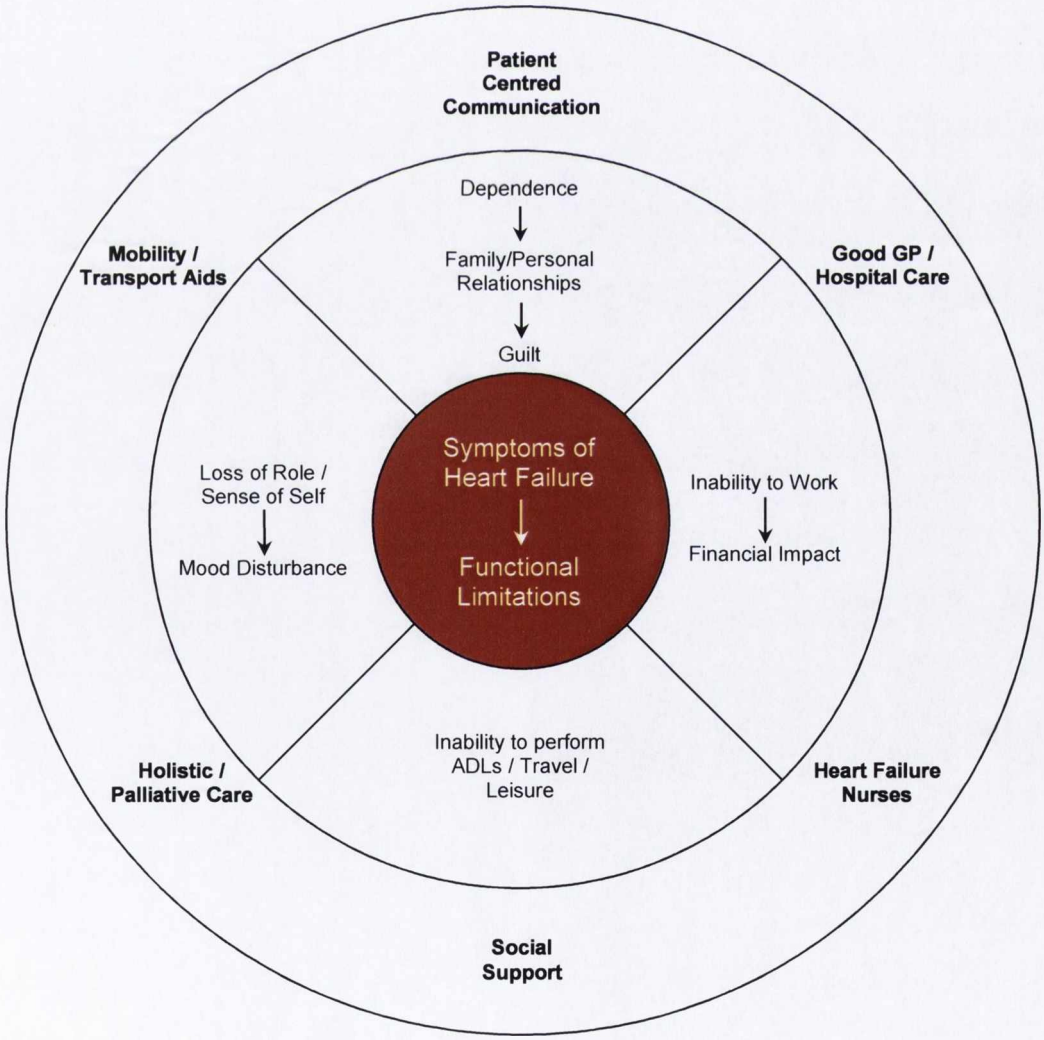


Figure 19

Diagram illustrating the core themes identified from the interviews in the centre, the impact of the core themes on patients lives in the middle circle and the outside factors which can influence quality of life on the outermost circle.

The diagram above (Figure 19) illustrates the conclusions and themes from the interviews. Symptoms of heart failure and functional limitations were the core themes. As a result of symptoms and functional limitations, patients experienced feelings of loss of sense of self and roles, dependence and its impact on personal and family relationships, inability to work, perform activities of daily living and enjoy travel and leisure. Although many of these themes were found in all three interviews, due to the small number of interviews data saturation was not achieved and further research in this area is required.

Chapter 6 – Discussion of results

Discussion of results from stage 1

The study population

The response rate for this postal questionnaire survey appears to be much lower than in previous studies. Typically response rates for postal questionnaire surveys in general practice, targeting patients with chronic disease, range from 45% to 85%.(Gott et al. 2006) (Smith et al. 1985) However, the studies measuring these response rates generally use one questionnaire and the target patients are younger than the cohort identified in this study. The completion of three individual quality of life measures, in addition to the demographic questionnaire may have reduced the number of respondents in our study. The questionnaire administration method may have also contributed to the low response rate. Previous research has shown that postal questionnaire surveys in general practice have a lower response rate than direct hand delivered administration. (Wensing, Smits & Van Montfort 1996) Direct administration was not feasible given the study time frame. The response rate could also have been improved by the use of reminder letters. Reminder letters and repeated mail shots were limited by ethical and time constraints.

Despite the low response rate, the responders in the study were representative of the heart failure population in general practice in Northern Ireland, the practices used were representative of Northern Ireland practices and the patients who responded were no different to the non-responders. The data from the primary outcome measure, the MLwHF, also indicates the study population was similar to other heart failure populations. The mean MLwHF total score across all NYHA groups in the study was 45.5, and the standard deviation was 26.1. Previous research reports very similar descriptive statistics in larger numbers of heart failure patients (mean MLwHF = 45.3, SD = 27.2). (Bennett et al. 2002) (Wensing, Smits & Van Montfort 1996)

The Questionnaires

Quality of life in patients with heart failure can be measured using disease specific and generic quality of life instruments. Individual instruments may have emphasis on certain quality of life domains and therefore measure different constructs. The study data shows how the quality of life instrument used will affect the outcome in certain patient populations, but also how patient factors may affect quality of life irrespective of the instrument used. A table summarising the quality of life scales and independent variables is shown below (Table 6).

QOL Instrument	Independent variables				
	Age	Gender	Martial	Co-morbidity	NYHA Class
Minnesota Living with Heart Failure Questionnaire	✓		✓	✓	✓
SF-12 Physical component summary		✓		✓	✓
SF-12 Mental component summary	✓	✓	✓		✓
Hospital Anxiety and Depression Scale	✓	✓	✓	✓	✓

Table 6

Table showing the independent variables which contributed to the variation in scores in the quality of life instruments used.

The relationship between marital status and quality of life demonstrates the importance of selecting an appropriate quality of life instrument. Marital status was a contributor to quality of life scores using the MLwHF, the HADS and the MCS scale from the SF-12. It did not contribute to quality of life scores in the SF-12 PCS. The SF-12 PCS measures the physical components of quality of life but it does not measure any emotional, psychological or mental domains. Marital status is a patient factor which would be expected to contribute to emotional,

psychological, mental or social domains of quality of life. It is unlikely to affect physical functioning and therefore will not contribute to quality of life if an instrument measuring predominantly physical outcomes is used.

The HADS was the only instrument which was affected by age, gender, marital status, co-morbidity and NYHA class. Psychological wellbeing is therefore highly influenced by disease, demographic and social factors. This is supported by previous research. Gott et al also found that depression was significantly associated with all quality of life outcomes.(Gott et al. 2006) A study examining quality of life in patients with heart failure (n=58) found that depressive symptoms had a greater impact on quality of life than severity of cardiac dysfunction or functional impairment.(Carels 2004) Further evidence suggests that patients with depression report a higher number of physical symptoms which in turn is associated with a decrease in quality of life.(Bekelman et al. 2007)

The disease specific MLwHF measures both physical and emotional dimensions of quality of life but did not show association with all the independent variables. Although there is substantial evidence of the reliability and validity of the MLwHF, Heo et al showed that its psychometric soundness could be improved with the removal of several items. (Heo et al. 2005)

NYHA Class/Disease severity

The strong association between NYHA class and quality of life is consistent with the findings of previous research in quality of life of patients with heart failure. Higher NYHA class was associated with a reduced quality of life in patients with heart failure in general practice in Northern Ireland. This finding is supported by several previous studies in secondary care (Hobbs et al. 2002, Juenger et al. 2002, Carels 2004) and in a study recruiting patients from general practice. (Gott et al. 2006) Gott et al found that in patients with heart failure recruited from general practice NYHA class was significantly associated with all quality of life outcomes, a finding confirmed by our study.

Increasing disease severity, as measured by NYHA class, has a detrimental effect on both physical and emotional components, as well as disease specific and generic quality of life issues. As disease severity increases patients would be expected to have a higher symptom burden and therefore greater functional limitation, leading to a global reduction in quality of life. This model would explain how NYHA class is significantly associated with quality of life and psychological wellbeing, irrespective of the instrument used. Hobbs et al found that this relationship can be influenced. By optimising treatment to improve NYHA class patients in their study showed an improved quality of life.(Hobbs et al. 2002)

The use of patient reported NYHA class as a marker of disease severity is not without flaws. By asking patients to grade their own NYHA class it could be argued that this is an indirect indication of how they view their quality of life. If this is the case then self-reported NYHA class and quality of life are synonymous.

Patient reported NYHA class may also not be a true reflection of disease severity or functional limitations. Patients rate their NYHA class higher than nurses.(Karlsson et al. 2008) The discrepancy between nurse and patient NYHA assessment has been shown to be associated with the patients degree of depression.(Karlsson et al. 2008) General practitioners do not routinely record NYHA in patient notes therefore patient reported NYHA class was necessary in this study. Despite the flaws in using patient reported NYHA class, patients' perceptions of functional status and their influence on quality of life are important, even if it is not an accurate measure of disease severity.

The effects of heart failure on quality of life can be attributed to symptoms (Rector, Anand & Cohn 2006), the stage of heart failure (Azevedo et al. 2008) and NYHA class (Hobbs et al. 2002). However the regression models show that the variation in quality of life scores in patients with heart failure may also be influenced by factors not related to heart failure.

Co-morbidity

Increasing levels of co-morbidity were associated with poorer outcomes on all instruments used. Co-morbidity was a significant confounder in all questionnaires except for the SF-12 MCS indicating that the level of co-morbidity not only impacts upon the physical and emotional domains of quality of life, but also on the degree of depressive and anxiety symptoms in patients with heart failure. Patients with 4 or more conditions had the poorest outcomes on all measures. These results correspond to findings from previous research. (Gott et al. 2006)

Co-morbidity would be expected to impact upon quality of life scores obtained from generic quality of life instruments. By their nature generic instruments aim to obtain an overall impression of quality of life across all domains and conditions. A greater number of co-morbid conditions would result in a greater range of possible quality of life effects and therefore poorer outcomes on a generic instrument. Although increasing level of co-morbidity resulted in poorer outcomes on the generic SF-12 MCS, it was not a significant contributor in the regression model. This could be explained by the domains included in the MCS. It measures mental components of quality of life which would be less likely to be influenced by multiple physical conditions than the SF-12 PCS in which co-morbidity was a significant contributor. However, the presence of co-morbid conditions was a contributor to the variation in the total HADS score and is

therefore associated with impaired psychological wellbeing in heart failure patients.

Interestingly co-morbidity was also a significant confounder in the MLwHF, a disease specific instrument. This instrument was designed to measure the effects of heart failure on an individuals' quality of life. The relationship between co-morbidity and heart failure disease specific quality of life is likely to be complex. Co-morbid conditions may not only produce similar symptoms to heart failure but the global impact of multi-morbidity may also play a role in affecting the domains included in the disease specific tool. In their study Gott et al also found that disease specific quality of life was influenced by co-morbidity. Patients in this study with four or more co-morbid conditions had much lower scores on the Kansas City Cardiomyopathy Questionnaire than those with one or no co-morbid conditions.

Patients with heart failure report a wide range of individual co-morbid conditions. The most common co-morbid condition reported was arthritis, although the type of arthritis was not clarified it is likely that patients were reporting osteoarthritis due to the age of the study cohort. Visual and hearing impairment would be relatively common in elderly patients. With the mean participant age of 73 years, it is hardly surprising that this was the second most common condition with 38.9% of participants reporting it as a co-morbid condition. The high prevalence of angina and lung disease in the study participants is to be expected given the aetiology of heart failure and the risk factors for its development. Very few

patients (4%) reported mental health disorders as a co-morbid condition despite the high levels of depression and anxiety on the HADS. This indicates that although heart failure patients suffer from depression and anxiety, few are given such a diagnosis. This highlights the need for healthcare professionals to be vigilant and screen for depression and anxiety in heart failure patients. Recognition and treatment of these conditions could improve the quality of life of patients with heart failure. The association of arthritis, blood disorders, gastro-intestinal disease in two of the four instruments could be due to the fact that these conditions were some of the most prevalent in study participants. Many of the co-morbid conditions were present in insufficient numbers to analyse. For example, psychiatric conditions were also associated with quality of life outcomes in 2 of the instruments despite only 4 patients having selected this as a co-morbid condition.

Marital Status

Single patients in this study had better outcomes in the disease specific and generic instruments as well as the HADS. In previous quality of life studies in patients with heart failure recruited from the community the impact of marital status was not explored. However a study examining heart failure mortality found that the presence of a relationship and its quality was a predictor of 8 year survival. (Rohrbaugh, Shoham & Coyne 2006) The presence of a life partner would be expected to contribute favourably to the social domains in quality of life instruments. However the presence of a poor relationship at home could also have a detrimental effect on quality of life and therefore being single could be protective. The number of single patients in the study was small (n=9) and therefore this could just be a spurious finding. Participants who were married or had a partner had better quality of life outcomes than those who were widowed who in turn had better outcomes than those who were divorced or separated. This does suggest personal relationships have some influence on quality of life. Marital status did not contribute to PCS outcomes, the only instrument which solely measured the physical component of quality of life. This indicates that the influence of marital status on quality of life of patients with heart failure appears to affect social and emotional domains rather than physical domains.

Age

Increasing age was associated with better quality of life, particularly in the disease specific instrument and in those which measured mental and psychological domains. The study hypothesis postulated that increasing age would be associated with poorer quality of life. The rationale for this was that elderly patients are more likely to have co-morbidity and higher levels of baseline disability than younger patients with heart failure. In addition to this many elderly patients have less social support and the combination of these factors was expected to be reflected in poorer quality of life scores. The poor representation of older patients in clinical trials in heart failure limits the availability of data on quality of life in elderly patients. The evidence which is available from previous research regarding age and quality of life in patients with heart failure is also conflicting.

In their study, recruiting patients over 60 years old with heart failure from primary care, Gott et al found that increasing age was associated with poorer quality of life outcomes. Older patients had lower scores on the physical and mental functioning scales of the SF-36 than the younger patients in this study but no association between age and disease specific quality of life was found. The median age of participants in this study was 77 years, a much older cohort than our study in which the median age was 74 years. The recruitment of patients exclusively over the age of 60 years could explain the discrepancy between this study's results and others reported in the literature.

An evaluation of the functional capacity and health related quality of life in patients (n=546) with heart failure from secondary care reported similar findings to our study. (Masoudi et al. 2004) Despite older patients in this study having higher NYHA classes and poorer functional capacities on a 6-minute walk test, they reported better quality of life outcomes at baseline than the younger patients. One disease specific instrument was used in this study, the Kansas City Cardiomyopathy Questionnaire. The MLwHF was used in a study performed in secondary care which also reported a significant association between age and better disease specific quality of life. (Rector, Anand & Cohn 2006)

Increasing age in the study was associated with increasing levels of co-morbidity ($p=0.04$) but there was no significant difference in NYHA class of older patients compared to younger patients. Despite this increasing age was associated with better quality of life. This suggests that although older patients with heart failure have similar functional capabilities to younger patients and higher levels of co-morbidity, these factors do not have as significant an effect on their quality of life. The acceptance of functional limitations may be one reason for this finding. Older patients may have lower expectations of acceptable levels of function. Therefore functional limitations have less impact on their reported quality of life. Younger patients on the other hand may feel more frustrated by reduced levels of function particularly as their peers have much higher levels of function.

Gender

Although, there was no significant difference between the gender of the responders and non-responders, females had a poorer response rate than males. Despite more females invited to participate in the study, the majority of respondents in the study were male. Gott et al also reported poorer response rates in women than in men. (Gott et al. 2006)

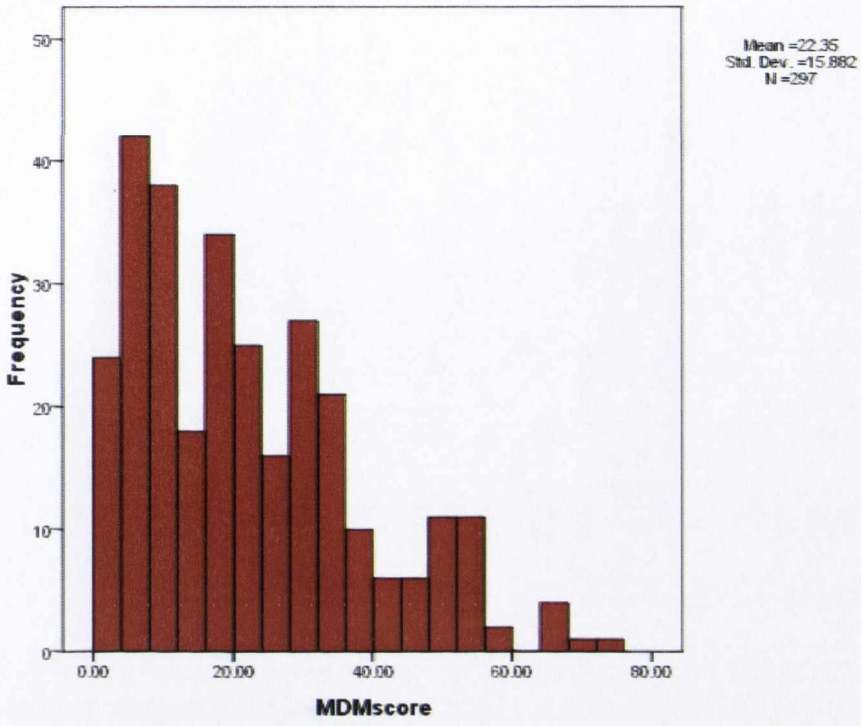
Females had poorer quality of life outcomes than males on the PCS, the MCS and the HADS. Other studies have reported poorer quality of life outcomes in women. (Friedman 2003, Stomberg, Martensson 2003) However like older patients with heart failure, women tend to be underrepresented in clinical trials (Heiat, Gross & Krumholz 2002, Krumholz 1998) and therefore conclusive evidence on the effect of gender on quality of life is not available. Rector et al was one such study which found no significant association between gender and quality of life. (Rector, Anand & Cohn 2006) Gott et al aimed to identify factors predictive of quality of life amongst older patients recruited from community settings. They found that women had poorer quality of life outcomes on the disease specific measure used and the SF-36 PCS but not the SF-36 MCS.(Gott et al. 2006) In contrast we found that females had poorer outcomes on both the SF-12 PCS and MCS as well as the HADS, but not on the disease specific measure. Gott's study was limited as they only sampled patients over the age of 60 years.

Being female was associated with poorer quality of life and in particular greater psychological morbidity. This suggests that female patients with heart failure are more sensitive to the impact of disease on mental and emotional health. The exact mechanism by which gender affects quality of life is not known and further work in this area is required.

Social Class

An unexpected finding of our study was the lack of association between social class and quality of life outcomes. In previous research in primary care socioeconomic group was significantly associated with disease specific and generic mental health scale but not with the generic physical functioning scale

Social class, as measured by the MDM score was not associated with quality of life or psychological distress in heart failure patients recruited from general practice in Northern Ireland. There was no significant difference in social class between the respondents and non-respondents but the heart failure population sampled in the study had a high frequency of lower socioeconomic groups (See Figure 20).


Mean =22.35
Std. Dev. =15.882
N =297
Frequency
MDMscore
0.00
20.00
40.00
60.00
80.00
0
10
20
30
40
50

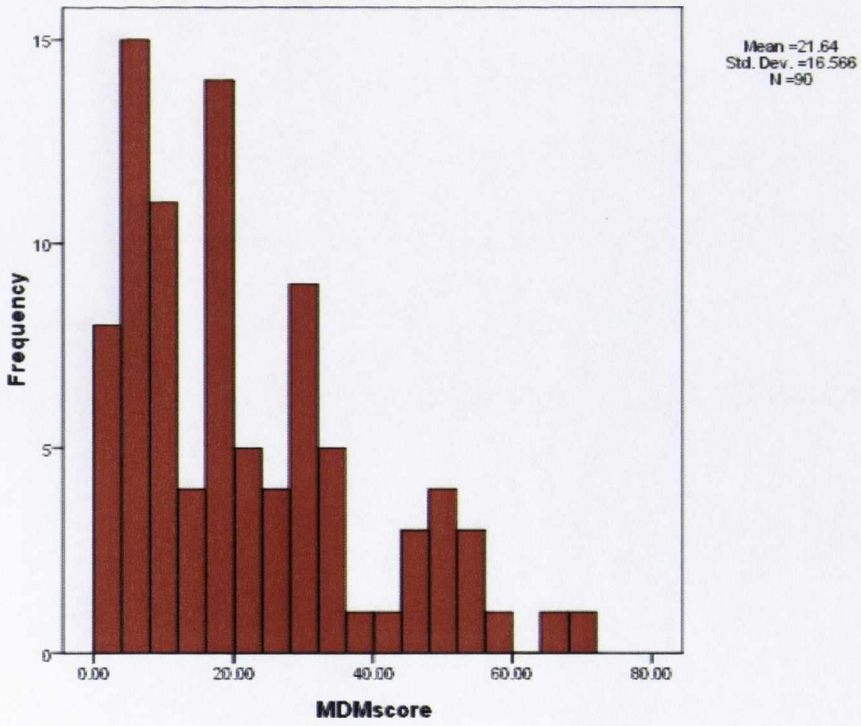

Mean =21.64
Std. Dev. =16.566
N =90
Frequency
MDMscore
0.00
20.00
40.00
60.00
80.00
0
5
10
15

Figure 20

Histograms showing the distribution of MDM score in the all patients sent the study information (above) and those who responded (below).

As illustrated in Figure 20 the majority of the population sampled and the final study population were in the lower MDM score brackets. This could be due to a higher prevalence of heart failure in lower socioeconomic groups or an unrepresentative sample in this study. However the lack of patients in the higher socioeconomic groups could explain the lack of association with quality of life. Perhaps the range of socioeconomic groups was not great enough to demonstrate a significant difference.

Discussion of results from stage 2 of study

Despite the limitation of our qualitative data the themes identified from the interviews were consistent with previous findings in patients with heart failure and chronic disease. The effects of functional limitations and symptoms of heart failure on quality of life are well known. A local qualitative study identified that patients with chronic illness face many difficulties due to deteriorating health status including decreased independence and social isolation. The patients in this study were found to have various unmet needs and had difficulty in accessing community services. (Fitzsimons et al. 2007)

The patients interviewed recognised the vital role of specialist heart failure support services, particularly heart failure nurses, in improving quality of life. Rich et al reported that patient education programmes, particularly heart failure nurse led interventions, had positive influences on quality of life outcomes. (Rich et al. 1995) In addition to this the support of heart failure nurses has been shown to positively influence levels of depression. (Martensson et al. 2005)

A strong theme which emerged from our interviews was the lack of effective communication between healthcare professionals and patients with heart failure. Communication was found to be lacking at the time of diagnosis, during hospital stays and when discussing prognosis.

"Most people with heart failure do not understand the cause or prognosis of their disease and rarely discuss end of life issues with their professional carers." (Murray et al. 2002)

In this community based qualitative study Murray et al found that patients with heart failure had a poorer understanding of their condition and prognosis and were less autonomous than those with lung cancer.

The need for better communication in heart failure was also highlighted by Rogers et al who reported that communication with heart failure patients and their subsequent understanding of their condition and symptoms was lacking.(Rogers et al. 2000) In a multicentre, post-hospitalisation interview study of heart failure patients in Slovenia n = 187, 89% were aware of their condition but only 61% reported satisfaction with the communication received regarding their clinical condition from medical staff.(Lainscak, Keber 2003) Patients also identified difficulties in communicating with doctors as a potential barrier to receiving appropriate information regarding prognosis.(Rogers et al. 2000)

The quantitative and qualitative findings of the study both highlight the poor quality of life in patients with heart failure. This may be adversely affected by disease severity, age, gender and co-morbidity but can also be positively influenced by the actions of doctors and other healthcare professionals. Patients have identified key areas which have helped them cope with their illness and these are supported in the literature. In addition to good quality medical care,

access to support services, contact with heart failure nurses, good communication and a holistic approach to heart failure management are areas which can make a difference to the patients' quality of life.

Individual patients with heart failure have different quality of life issues and unmet needs. It is therefore vital that care is tailored to the individual. There is evidence that patients with heart failure have as poor a prognosis and symptom burden as patients with cancer. (Nordgren, Sörensen 2003, Stewart et al. 2001) Heart failure patients also report similar problems to patients with conditions managed by palliative care teams, such as uncontrolled symptoms, progressive decline, dependence and poor quality of life. However, traditionally patients with heart failure have been unlikely to receive specialist palliative care. The importance of palliative care in heart failure management is beginning to be recognised. The National Service Framework for Coronary Heart disease (Department of Health 2000) identified the need for patients with unresponsive heart failure to receive appropriate palliative care. This can be challenging to implement in the community with one barrier being general practitioners reluctance to initiate due to difficulties in accurately predicting prognosis in heart failure. (Hanratty et al. 2002)

The principles of palliative care can be used to improve quality of life in patients with varying severity of heart failure. The centre of this treatment model is good communication, identified as a problem area in our study interviews. General practitioners and hospital doctors need to recognise the importance of

combining treatment modalities with the holistic approach of palliative care and at the same time keeping the patient informed and involved. The introduction of earlier access to support for patients and their families can reduce the feelings of burden and make functional limitations less disabling.

Improvements in quality of life can be achieved through better symptom control by adjusting medical therapy but patients and their families also require the support to help them cope with the daily burden of this disease. For example involving healthcare professionals such as nursing care, social workers, and occupational therapists to address social care needs and improve quality of life. The qualitative interviews indicate that it is these services which patients and their families value the most. Although valuable data was gathered from these interviews further work in this area is required.

Strengths of the study

This study highlights the impact of heart failure on quality of life and how unmet needs influence the daily life of individuals with heart failure and their families. Despite providing data on an area of clinical importance it is also the first study of its kind in general practice in Northern Ireland and provides valuable information which was not previously available.

Previous studies in general practice have been limited due to the difficulty in identifying patients with an accurate diagnosis of heart failure. The introduction of heart failure registers, which require an objective measure of heart failure allowed this study to recruit patients from primary care with a definite diagnosis. Patients under the age of 18 years were excluded but all other age groups were included. Previous studies in secondary care often excluded these older patients. It is the first study of quality of life in heart failure patients recruited from the community to report increasing quality of life with increasing age.

Limitations of the study

The main limitations of this study are the cross-sectional design and the small study size. The sample size calculation was based on the likely effect size for the MLwHF and although this sample size was achieved, the total study population was still small given the cross-sectional design.

Despite the results showing that there were no significant differences in the respondents and non-respondents in this study, there may have been selection bias. The patients who responded to the questionnaire survey may have been more motivated and had a better quality of life than those who did not respond.

The NYHA class for each patient was obtained from the demographic questionnaire. A NYHA scale in lay terms was included and patients were asked to select the class which best applied to them. There may be an overlap in the self-reported NYHA class and the perceived quality of life. The use of this method to indicate disease severity may therefore be flawed.

The MLwHF is validated as a complete tool, the individual questions and subscales cannot be used in isolation. Although it was designed to measure the effect of heart failure on quality of life it may have been difficult for patients to separate the symptoms of heart failure and any co-morbidities.

A question on the MLwHF regarding the influence of heart failure on work ability caused some confusion. Many patients omitted this question as they were past retirement age. Therefore these individuals may have had lower overall scores than patients of working age.

The finding that single patients had better quality of life outcomes than those in all other marital groups was an interesting observation. However the small sample size and in particular the small number in this group, limited the ability to analyse this in greater detail.

Heart failure registers allowed identification of patients with a confirmed diagnosis of heart failure. The strength of the study data could have been improved by obtaining an objective measurement of cardiac function form the patients' medical records. Although the consent forms allowed this to be done, time constraints limited the collection of this data.

Time constraints also inhibited collection of more data in stage 2 of the study. Data saturation was not achieved in the qualitative interviews. As a result the qualitative data can only be used to inform the stage one data and provide a focus for further research in this area.

Conclusions of questionnaire survey

Quality of life in patients with heart failure varies greatly and is dependent on disease and patient factors. The quality of life instruments used in this study obtained information on a variety of quality of life domains and concepts and demonstrated that different disease and patient factors are important depending on the instrument used (See Table 6).

Disease severity, as measured by self-reported NYHA class was the most significant independent variable. Higher NYHA class resulted in detrimental effects on both physical and emotional components, as well as disease specific and generic quality of life areas. However NYHA class may not be a reliable marker of disease severity and may indirectly represent quality of life if self-reported by patients.

Patients with heart failure recruited from general practice have high levels of co-morbidity (77% of participants had 2 or more co-morbid conditions) and a wide range of individual co-morbid conditions. Increasing levels of co-morbidity are associated with poorer quality of life outcomes in patients with heart failure . Co-morbidity has a detrimental effect on physical quality of life in patients with heart failure and increased co-morbidity is also associated with impaired psychological wellbeing.

Marital status contributes to quality of life in patients with heart failure. It was a significant contributor to quality of life outcomes in the MLwHF, the SF-12 MCS and the HADS. Marital status did not contribute to PCS outcomes, the only instrument which solely measured the physical component of quality of life. Single patients in this study had better quality of life outcomes than those who were married or lived with a partner but the number of single patients was small. Those who were widowed, divorced or separated had much poorer outcomes than the participants who were single or in a relationship. Marital status therefore contributes to quality of life in heart failure patients, but appears to affect social and emotional domains more than physical domains.

The average age of patients in the study was 73 years, with the oldest participant aged 90 years. Age was found to contribute to variation in the MLwHF, the MCS and the HADS scores. The older participants in the study had better results in terms of quality of life and psychological wellbeing than younger participants. This may be due to older patients accepting functional limitations and having lower expectations of physical and emotional health.

Social class, as measured by the MDM score was not associated with quality of life or psychological distress in heart failure patients recruited from general practice in Northern Ireland.

Despite inviting more females to participate in the study, the majority of respondents in the study were male. Gender was found to be a contributing

factor in the PCS, the MCS and the HADS. It was not a significant confounder in the disease specific instrument, the MLwHF. Being female was associated with poorer quality of life and in particular greater mental and psychological morbidity in patients with heart failure.

Quality of life and psychological wellbeing in patients with heart failure is closely associated with disease severity and the presence of co-morbid conditions. Patients who are widowed, divorced or separated have poorer outcomes than those who are single or in relationships and females have poorer quality of life than males. Younger patients report poorer quality of life and more psychological distress than older patients.

Conclusion of patient interviews

Patients with advanced heart failure (NYHA class IV) report significant functional limitations and have complex unmet needs. The symptoms of heart failure and the progressive disease process results in reduced levels of physical and emotional functioning. As a result of this patients experience a loss of sense of self and of traditional roles. They become increasingly dependent on family and partners and this may result in feelings of guilt. Other consequences of increasing functional limitation include the inability to work and the impact on finances, travel and leisure.

The quality of life of patients with heart failure and their functional limitations may be improved through high quality, holistic multidisciplinary care. Patients value the input of heart failure nurses and support services which help maintain their independence. Patients with heart failure have fears for the future and they recognise the sub-optimal levels of communication delivered by healthcare professionals.

Chapter 7 - Summary of Thesis

Introduction

- Congestive heart failure is a clinical condition which results in significant morbidity and mortality.

- The incidence of heart failure is directly associated with increasing age. As life expectancy in the United Kingdom is increasing the incidence of heart failure is expected to rise.

- Heart failure has a detrimental effect on quality of life. The symptoms of heart failure explain a large proportion of variation in quality of life but other demographic variables are thought to also contribute.

- Quality of life is both subjective and multidimensional. It must be measured from the patient's perspective and information on various aspects of a patient's life is required for its adequate assessment. Questionnaires are a useful tool in measuring quality of life and may be generic or disease specific in nature.

- Most of the quality of life data for patients with heart failure has been obtained from trials in secondary care. Women, older patients and those with co-morbidity are under-represented in these studies. There are few studies reporting the impact of heart failure on quality of life in community settings.

- The introduction of the Quality and Outcomes Framework in general practice has improved the need for a definite diagnosis of heart failure using objective measures and the recording of heart failure in patients records. This facilitates more accurate identification of patients with heart failure for research.

- Qualitative research exploring quality of life in heart failure has shown patients recognise the impact of positive and negative influences on quality of life.

- The needs of patients with advanced chronic disease, such as heart failure, are complex and a more timely implementation of palliative care is necessary in order to meet these needs.

Summary of results

- Nine practices in Northern Ireland participated in a study which aimed to explore quality of life and unmet needs of patients with heart failure recruited from the community.

- 297 patients with heart failure were invited to participate in the study and 90 responded. The study response rate was 30.3%.

- The mean age of participants was 73 years, the study population had more males than females, the most common NYHA classes were II and III and most patients were married or lived with a partner. Over 77% of participants had 2 or more co-morbid conditions.

- There were no significant difference between the respondents and non-respondents in terms of age ($p=0.827$), gender ($p=0.274$) and social class($p=0.383$).

- Patients in NYHA classes I and II had significantly better quality of life scores on the MLwHF ($p<0.001$), the SF-12 PCS ($p<0.001$) and the SF-12 MCS ($p<0.001$) than those in NYHA classes III and IV.

- Patients in NYHA classes I and II also had significantly lower levels of psychological morbidity on the HADS ($p<0.001$) than those in NYHA classes III and IV.

- The disease, demographic and social factors included in this study were responsible for 55% of the variation in quality of life scores measured by the disease specific MLwHF questionnaire.

- The variables which contributed to MLwHF scores were NYHA class, age, co-morbidity and marital status. Those with lower NYHA class, older patients, those with fewer co-morbid conditions and single patients had better quality of life as measured by the MLwHF.

- The independent variables used in the study were responsible for 49% of the variation in SF-12 PCS scores.

- The variables which contributed to SF-12 PCS scores were NYHA class, gender and co-morbidity. Those with lower NYHA class, male patients and those with lower levels of co-morbidity had better quality of life as measured by the SF-12 PCS.

- The independent variables used in the study were responsible for 36% of the variation in SF-12 MCS scores.

- The variables which contributed to SF-12 MCS scores were NYHA class, age, gender, and marital status. Those with lower NYHA class, older patients, males and single patients had better quality of life as measured by the SF-12 MCS.

- The independent variables used in the study contributed to 48% of the variation in HADS scores.

- The variables which contributed to HADS scores were NYHA class, age, gender, co-morbidity and marital status. Those with lower NYHA class, older patients, males, those with lower levels of co-morbidity and single patients had better psychological wellbeing as measured by the HADS.

- Symptoms of heart failure and the resulting functional limitations are the core negative influences on quality of life in patients with heart failure.

- Patients reported that these core influences impact on quality of life through dependence, loss of sense of self and roles, an inability to work, inability to perform activities of daily living and enjoy leisure and travel.

- Personal relationships and good family support are important in helping patients cope with the impact of heart failure on quality of life. However dependence on partners and families may result in feelings of guilt for patients with heart failure.

- Positive influences which can help improve quality of life for patients with heart failure include good GP and hospital care, social support, the availability of heart failure nurses, the use of holistic or palliative care, patient centred communication and the provision of mobility or transport aids.

Summary of conclusions

- Quality of life in patients with heart failure varies greatly and is dependent on disease, patient factors and the instrument which is used to assess it.

- Disease specific quality of life in patients with heart failure in Northern Ireland is affected by disease severity, age, co-morbidity and marital status.

- The physical and mental components of quality of life in patients with heart failure using a generic tool are affected by disease severity, gender and disease severity

- Psychological wellbeing in patients with heart failure is affected by disease severity, age, gender, NYHA class, level of co-morbidity and marital status.

- Disease severity, as measured by self-reported NYHA class was the most significant independent variable. Higher NYHA class resulted in detrimental effects on quality of life measured by all instruments. NYHA class may not be a reliable marker of disease severity and may indirectly represent quality of life if self-reported by patients.

- Patients with heart failure recruited from general practice have high levels of co-morbidity and increasing levels of co-morbidity are associated with poorer quality of life outcomes.

- Marital status contributes to quality of life in patients with heart failure. Single patients in this study had better quality of life outcomes and those who were divorced or separated had the poorest outcomes. The number of single patients was however small. Marital status affects social and emotional domains of quality of life more than physical domains.

- Older patients with heart failure have better outcomes in terms of quality of life and psychological wellbeing than younger patients. This may be due to older patients' acceptance of functional limitations and lower expectations of physical and emotional health.

- Female patients with heart failure have a poorer quality of life than males, especially in the mental domains.

- Patients with advanced heart failure (NYHA class IV) report significant functional limitations and have complex unmet needs.

- The quality of life of patients with heart failure and their functional limitations may be improved through high quality, holistic multidisciplinary care with good communication at the centre of this care.

Further Research

Previous studies examining quality of life of patients with heart failure in the community were limited due to difficulties with recruitment. Despite using heart failure registers to accurately identify patients, our study was limited by its small sample size. Therefore a larger cross sectional or longitudinal study exploring quality of life in patients with heart failure recruited from community heart failure registers is required.

Unmet needs in patients with heart failure need addressed to improve standards of care. To determine the needs which are important to patients a larger qualitative study is required. This should include both a wide range of patients and those with varying disease severity.

Appendices

Appendix 1 Practice Invitation Letter

Dr. X and Partners
Practice Address

Date

Dear Dr. X,

Following your conversation with Dr. Gilliland, we are conducting a study exploring quality of life and unmet needs of heart failure patients in primary care and wish to invite your practice's participation. The practice has been selected as one of ten general practices from across Northern Ireland.

Study title: Exploring quality of life and unmet needs of patients with heart failure in a General Practice population.

The aims of this study are to gather quality of life data from heart failure patients in primary care across Northern Ireland and assess unmet needs of a small group of these patients through individual qualitative interviews.

The primary investigator is Dr. Martina Monaghan, research registrar in General Practice, supervised by Dr. A. Gilliland and Dr. M. Cupples at Queen's University Belfast.

Please find enclosed a pack including practice and patient information sheets and the practice reply slip. We would be grateful if you could indicate whether or not you wish to participate by completing and returning the enclosed reply slip.

Many Thanks,

Dr Martina Monaghan/ Dr Drew Gilliland/ Dr Margaret Cupples
Department of General Practice
Queen's University Belfast
1 Dunluce Avenue
Belfast BT9 7HR
Tel – 02890204301
Email – mmonaghan@doctors.org.uk

Appendix 2 Practice Information Sheet

Exploring quality of life and unmet needs of patients with heart failure in a General Practice population

PRACTICE INFORMATION SHEET

Rationale and study objectives

Congestive heart failure is a condition which results in considerable morbidity and mortality. [1] The detrimental effect of heart failure on quality of life has been recognised for many years [2] with quality of life data being collected through clinical trials in secondary care. However, due to pressure on secondary care services, heart failure patients are now increasingly being managed in primary care. This study will obtain quality of life data from patients with heart failure of varying severity (New York Heart Association Classes 1-4) in the Northern Ireland General Practice population.

There is evidence that patients with heart failure currently receive sub-optimal levels of supportive care and have complex unmet needs.[3, 4] This study aims to determine patients' unmet needs through semi-structured interviews. This information is not available currently for General Practice patients in Northern Ireland and is necessary if care for this group of patients is to be improved.

What will happen if our practice agrees to participate in this study?

1. If you agree to participate you will firstly be asked to identify patients with heart failure from your disease register who fulfil the study inclusion criteria. These are as follows;

    - Patients with diagnosis of heart failure as identified from practice heart failure register.
    - Age greater than 18 years

- Physically able to complete a questionnaire
- No evidence of cognitive dysfunction
- Able to consent to participation in study
- English speaking

2. The practice will be provided with prepared study information packs which include the following documents:

    - Information for patient on background and aims of study
    - Question sheet on patient factors e.g. age, sex, postcode, marital status, co-morbidities and perceived NYHA class.
    - Short - Form 12 (SF-12) quality of life questionnaire
    - Hospital Anxiety and Depression scale (HADS)
    - Minnesota Living with Heart Failure Questionnaire (MLwHF)
    - Consent forms for;
    - Access to patient's medical records
    - Willingness to be contacted by the researcher for further discussion of experiences in second stage of the study
    - Stamped addressed envelope for return of survey to researcher

The questionnaires should take no more than 30 minutes in total to complete.

3. These information packs would be sent to the identified patients by the practice. (Postage costs will be covered by the research team)

4. If a patient from the practice consents to participate their medical records would be viewed by the researcher Dr Martina Monaghan at a mutually convenient date and time. Only information pertinent to the study will be used.

5. If a patient does not wish to participate we will ask for some basic anonymised data to analyse for possible response bias. This information would be limited to age, gender and postcode.

Please see the patient information leaflet for further information and if you have any queries do not hesitate to contact the research team at the number below.

Dr Martina Monaghan
Department of General Practice
Queen's University Belfast
1 Dunluce Avenue

Belfast BT9 7HR
Tel – 02890204301
Email – mmonaghan@doctors.org.uk

References

(1) Davis RC, Hobbs FDR and Lip GYH. ABC of Heart Failure: history and epidemiology. BMJ 2000; 320: 39-42.
(2) Hinton JM. The physical and mental stress of dying. QJM 1963; 32: 1-21.
(3) Ward C. The need for palliative care in the management of heart failure. Heart 2002; 87: 294-298.
(4) Fitzsimons et al. The challenge of patients' unmet care needs in the final stages of chronic illness. Palliative Medicine 2007; 21: 313-322.

GP reply slip

Practice name.....

We would like to participate in this study ☐

We do not wish to participate in this study ☐

Appendix 4 Practice Reminder letter

Dr. X and Partners
Practice Address

Date

Dear Dr. X and Partners

Further to the letter we sent you on (Date), please find enclosed a copy of this letter and a reply slip. We would be grateful if you could indicate whether or not you wish to participate in this study.

Many Thanks,

Dr Martina Monaghan/ Dr Drew Gilliland/ Dr Margaret Cupples
Department of General Practice
Queen's University Belfast
1 Dunluce Avenue
Belfast BT9 7HR
Tel – 02890204301
Email – mmonaghan@doctors.org.uk

Appendix 5 Participant invitation letter

Dr X and Partners (Patient's GP)
GP address

Date

Dear

The practice is involved in a study being carried out by Dr. Martina Monaghan at Queen's University, Belfast.

The study aims to find out how people's lives are affected by heart trouble. Patients with all types of heart trouble are being invited to take part by answering the questionnaires enclosed and returning them in the pre-paid envelope provided.

It is hoped that the results of this study will highlight how heart trouble affects individuals' lives and identify areas in which care could be improved.

If you would like to take part in this questionnaire study please read the information leaflet enclosed and return your completed forms in the pre-paid envelope. Thank you for taking the time to read this letter. If you have any questions about the study feel free to contact Dr. Monaghan at the number below. If you decide not to take part in the study your medical care will not be affected and your personal details will not be released to the researchers.

Yours sincerely,

Dr. X and Partners

Dr. Martina Monaghan

Department of General Practice

Dunluce Health Centre

Queen's University Belfast

BT9 7HR

Tel – 02890204301

Email – mmonaghan@doctors.org.uk

Appendix 6 Participant information sheet

Study title: Quality of life and needs of patients with heart trouble

Dear

My name is Dr. Martina Monaghan. I am a medical doctor currently enrolled in a master's course in research at Queen's University, Belfast.

You have been invited to take part in this study looking at how heart trouble affects people's lives. Before you decide to participate it is important for you to understand why the study is being carried out and what it involves. Please read the following information and discuss it with others if you wish. If anything is unclear, or if you would like more information please contact me at the following number – 02890204301.

What is the purpose of the study?
I am doing this study to find out how heart trouble affects people's daily lives and how they feel their care could be improved.

Why have I been chosen?
Your GP practice has agreed to take part in this study and has been asked to forward this information to patients in their practice with a history of heart trouble.

What are the benefits of taking part?
Although there is no direct benefit to you by participating in the study, by taking part you will be helping us understand more about how heart disease affects people's lives. The answers to your questions will give us valuable information about this. Through the results of this study we hope that doctors will have a greater insight into what is important to the patient with heart trouble and we may be able to make suggestions to improve care.

What will happen to me if I take part?

1. On the following pages are some questions about yourself and how heart trouble affects your daily life. Please answer all these questions as best you can and return them with the consent form in the envelope provided. The questions should take about 20-30 minutes to complete. If you wish this is all you have to do.

2. As part of the study a small number of people will be selected to discuss areas were they feel their needs are not being met. I will visit these patients in their own home at a time which suits them. If you do not wish to be involved in this part of the study please tick the relevant box on the consent form. Unfortunately not everyone who is interested in being involved in this part of the study will be selected initially but there may be the opportunity to involve more people at a later date.

3. On the consent form you will notice I have asked for your permission to access your records at the practice. This is important so I can identify your type of heart trouble and any other medical conditions which could affect you, for example lung disease, diabetes etc

What will happen if I don't take part?
Your participation in this study is entirely voluntary. If you decide not to take part or if you later decide to withdraw from the study at any time:

- You can do so freely without obligation
- You do not have to give a reason
- Your care will not be affected in any way

Will my information be kept confidential?
All information relevant to you will be treated confidentially and recorded anonymously. However, if you reveal some information that causes the researcher to be concerned regarding your welfare, this may need to be discussed with your own GP.

What happens to the results of this study?
I hope to eventually get the results of this study published. In any report or publication of the study results, you will not be identified.

Who is organising the research?
This research is taking place at the Department of General Practice, Queens University of Belfast. The study is funded by the Research and Development office, Northern Ireland.

What should I do now?
If you would like to participate, please:

- Answer the questions on the following pages

- Sign the consent form and indicate whether you wish to be considered for the later discussion
- Return both in the envelope provided

If you have any questions or difficulties in answering the questions please do not hesitate to contact me using the details below.

Complaints

If you have a concern about any aspect of this study, you should speak to the researcher whose details are provided below. If you remain unhappy or do not wish the researcher to be aware of your complaint, you can complain through the NHS complaints procedure

Dr. M. Monaghan
Research Registrar
Department of General Practice
Queen's University Belfast
Dunluce Health Centre
Belfast
BT9 7HR
Tel: 02890204301
Email – mmonaghan@doctors.org.uk

STUDY CONSENT FORM

I.....have read the information and agree to participate in this study. I understand I can withdraw at any time. I give my permission for my medical notes to be viewed by the researcher.

Signed.....
Date.....

Please state below whether you would like to be involved in further discussion about how heart trouble affects your daily life, as detailed in the information sheet.

I would be willing to discuss my experiences with Dr. Monaghan at a later date ☐

I am not willing to be involved in discussion of experiences at a later date ☐

Appendix 8 Participant demographic questionnaire

Demographic questionnaire

Thank you for deciding to take part in this study. On the following pages are some questions about how your heart trouble may impact on your everyday life. Before completing these it is important for us to know a little bit about you.

The information you provide will be kept confidential and will only be used for the purpose of the study.

Age .....

Gender Female
Male

Postcode .....

Marital status
Single ☐
Married ☐
Widowed ☐
Live with partner ☐
Divorced ☐
Seperated ☐

Do you have any other health problems? Please tick as many of the boxes below which apply to you. If you suffer from a health problem which is not listed here please write it in the box provided.

Angina	☐	Diabetes	☐
Kidney disease	☐	Hearing/Visual impairment	☐
Arthritis	☐	Cancer	☐
Blood disorders	☐	Stroke/ Brain disorder	☐
Epilepsy	☐	Mental Health problems	☐
Asthma	☐	Stomach/bowel problems	☐
Other lung problems	☐		

Which of the following categories would best describe how your heart trouble impacts on your level of activity:

I have no problems performing normal physical activity ☐

I am comfortable at rest but ordinary activity makes me breathless and tired ☐

I am comfortable at rest but less than ordinary activity makes me breathless and tired ☐

I am unable to carry out any physical activity without discomfort/ I am breathless at rest ☐

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.
Thank you for completing this survey!

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b. Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3

3. **During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. **During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. **During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Appendix 12 Draft Interview Schedule

Draft interview schedule

Opening statement

Mr/Ms X, today we are going to talk about how your heart trouble affects your daily life and if you feel things might be improved.

Questions

Tell me about a typical day

What are the main problems you face at the moment due to your heart trouble?

How do you manage around the house?

Do you get out of the house?

What has helped you cope with your heart trouble?

Have you had any problems getting help in any way?

Who do you currently see with regard to your heart trouble e.g. GP/ Hospital Dr. / District Nurse/ Heart failure nurse?

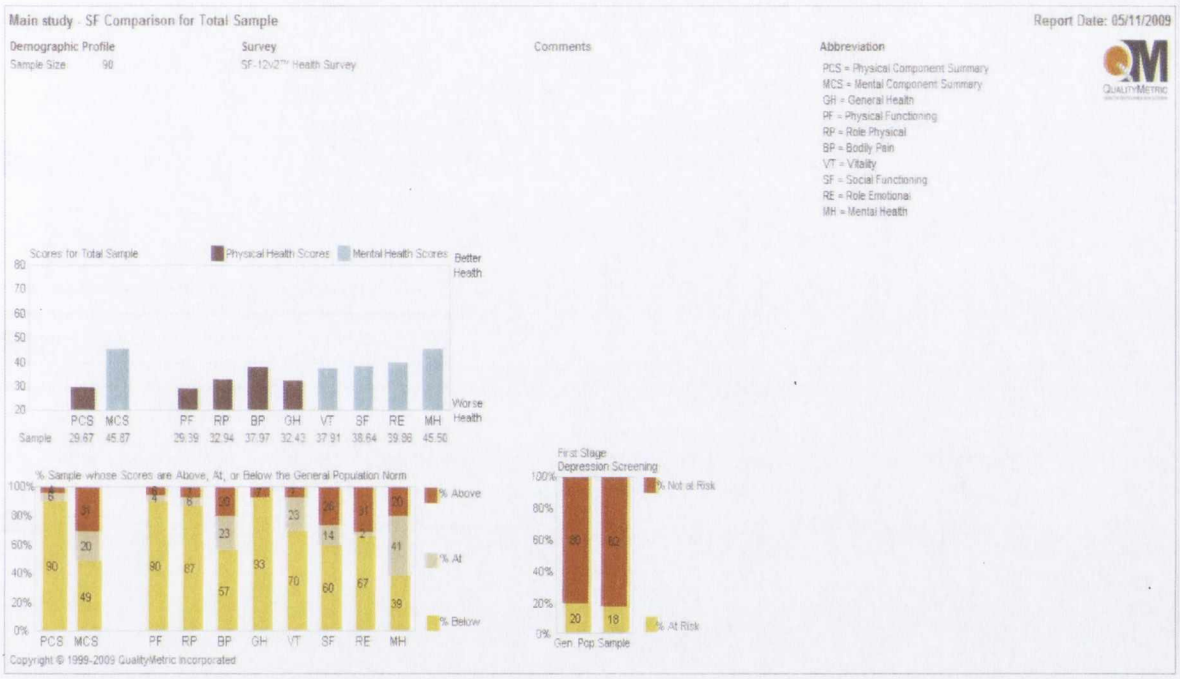
Is there anything you would like to see available for people with heart trouble that you currently don't have access to?

Do you have any needs which you feel aren't being met at the moment?

What are your thoughts/ feelings on the support you receive?

Is there anything else you would like to talk about?

Appendix 13 SF-12 Aggregate report



References

Addington-Hall, J.M. & McCarthy, M. 1995, "Regional study of care for the dying: methods and sample characteristics", *Palliative medicine,* vol. 9, pp. 27-35.

Azevedo, A., Bettencourt, P., Alvelos, M., Martins, E., Abreu-Lima, C., Hense, H. & Barros, H. 2008,."Health-related quality of life and stages of heart failure", *International journal of cardiology,* vol. 129, no. 2, pp. 238-244.

Bekelman, D.B., Havranek, E.P., Becker, D.M., Kutner, J.S., Peterson, P.N., Wittstein, I.S., Gottlieb, S.H., Yamashita, T.E., Fairclough, D.L. & Dy, S.M. 2007, "Symptoms, Depression, and Quality of Life in Patients With Heart Failure", *Journal of cardiac failure,* vol. 13, no. 8, pp. 643-648.

Bennett, S.J., Oldridge, N.B., Eckert, G.J., Embree, J.L., Browning, S., Hou, N., Deer, M. & Murray, M.D. 2002, "Discriminant properties of commonly used quality of life measures in heart failure", *Quality of Life Research,* vol. 11, pp. 349-359.

Berry, C. & McMurray, J. 1999, "A Review of Quality-of-Life Evaluations in Patients with Congestive Heart Failure", *PharmacoEconomics,* vol. 16, no. 3, pp. 247-271.

Bjelland, I., Dahl, A.A., Haug, T.T. & Neckelmann, D. 2002, "The validity of the Hospital Anxiety and Depression Scale: An updated literature review", *Journal of psychosomatic research,* vol. 52, no. 2, pp. 69-77.

Bosworth, H.B., Steinhauser, K.E., Lindquist, J.H., Grambow, S.C. & Oddone, E.Z. 2004, "Congestive heart failure patients' perceptions of quality of life: the integration of physical and psychological factors.", *Aging & Mental Health,* vol. 8, no. 1, pp. 83-91.

Brazier, J.E., Harper, R. & Jones, N.M.B. 1992, "Validating the SF-36 health survey questionnaire: new outcome measure for primary care", *British Medical Journal,* vol. 305, pp. 160-164.

British Heart Foundation 2007, 17/07/07-last update, *Economic Costs of Heart Failure*. Available: www.heartstats.org [2007, November] .

British Heart Foundation 2004, 29th June-last update, *Hospitalisations for heart failure*. Available: http://www.heartstats.org/datapage.asp?id=861 [2008, 18th September] .

Bunevicius, A., Peceliuniene, J., Mickuviene, N., Valius, L. & Bunevicius, R. 2007, "Screening for Depression and Anxiety Disorders in Primary Care Patients", *Depression and Anxiety,* vol. 24, pp. 455-460.

Butler, J. 2007, "An introduction to heart failure and its management", *British Journal of Cardiac Nursing,* vol. 2, no. 7, pp. 318-321.

Cameron, I., Crawford, J., Lawton, K. & Reid, I. 2008, "Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care", *British Journal fo General Practice,* vol. 58, no. 566, pp. 32-36.

Carels, R.A. 2004, "The association between disease severity, functional status, depression and daily quality of life in congestive heart failure patients.", *Quality of Life Research,* vol. 13, pp. 63-72.

Cella, D.F. 1994, "Quality of life: concepts and definition", *Journal of pain and symptom management,* vol. 9, no. 3, pp. 186-192.

CIBIS Investigators and Committees 1994, "A randomised trial of beta blockade in heart failure: the cardiac insufficiency bisoprolol study (CIBIS)", *Circulation,* vol. 90, pp. 1765-1773.

Coons, S.J., Rao, S., Keininger, D.L. & Hays, R.D. 2000, "A comparative review of generic quality-of-life instruments", *PharmacoEconomics,* vol. 17, no. 1, pp. 13-35.

Cowie, M.R., Struthers, A.D., Wood, D.A., Coats, A.J., Thompson, S.G. & Poole-Wilson, P.A. 1997, "Value of natriuretic peptides in assessment of patients with possible new heart failure in primary care", *Lancet,* vol. 350, pp. 1349-1353.

Cowie, M.R., Wood, D.A., Coats, A.J.S., Thompson, S.G., Poole-Wilson, P.A., Suresh, V. & Sutton, G.C. 1999, "Incidence and aetiology of heart failure; a population-based study", *European Heart Journal,* vol. 20, no. 6, pp. 421-428.

Davis, M.P., Albert, N.M. & Young, J.B. 2005, "Palliation of heart failure", *The American Journal of Hospice & Palliative Care,* vol. 22, no. 3, pp. 211-222.

Davis, R.C., Hobbs, F.D.R. & Lip, G.Y.H. 2000, "ABC of heart failure: History and epidemiology", *BMJ,* vol. 320, no. 7226, pp. 39-42.

Department of Health 2000, "Coronary Heart Disease: National Service Framework for Coronary Heart Disease" in Department of Health, London.

Department of Health, Social Services and Public Safety, Northern Ireland 2007, April-last update, *Raw Prevalences for Northern Ireland*. Available: www.dhsspsni.gov.uk.

Department of Health, Social Servies and Public Safety 2009, , *Quality and Outcomes Framework Achievement Data at General Practice Level 2007/2008*. Available: http://www.dhsspsni.gov.uk/pc_-_practice_qof_data_2008 [2008, November] .

Dunderdale, K., Thompson, D.R., Miles, J.N.V., Beer, S.F. & Furze, G. 2005, "Quality-of-life measurement in chronic heart failure: do we take account of the patient perspective?", *European Journal of Heart Failure,* vol. 7, no. 4, pp. 572-582.

Ellis, C., Gnani, S. & Majeed, A. 2001, "Prevalence and management of heart failure in General Practice in England and Wales, 1994-1998.", *Health Statistics Quarterly,* vol. 11, pp. 17-24.

Eng, J. 2003, "Sample Size Estimation: How Many Individuals Should Be Studied?", *Radiology,* vol. 227, no. 2, pp. 309-313.

Fitzsimons, D., Mullan, D., Wilson, J.S., Conway, B., Corcoran, B., Dempster, M., Gamble, J., Stewart, C., Rafferty, S., McMahon, M., MacMahon, J., Mulholland, P., Stockdale, P., Chew, E., Hanna, L., Brown, J., Ferguson, G. & Fogarty, D. 2007, "The challenge of patients' unmet palliative care needs in the final stages of chronic illness", *Palliative medicine,* vol. 21, no. 4, pp. 313-322.

Friedman, M. 2003, "Gender differences in the health related quality of life of older adults with heart failure.", *Heart & Lung,* vol. 32, pp. 320-327.

Garin, O., Ferrer, M., Pont, A., Rue, M., Kotzeva, A., Wiklund, I., Van Ganse, E. & Alonso, J. 2009, "Disease-specific health-related quality of life questionnaires for heart failure: a systematic review with meta-analyses", *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation,* vol. 18, no. 1, pp. 71-85.

Gorkin, L., Norvell, N.K., Rosen, R.C., Charles, E., Shumaker, S.A., McIntyre, K.M., Capone, R.J., Kostis, J., Niaura, R., Woods, P., Hosking, J., Garces, C., Handberg, E., Ahern, D.K., Follick, M.J. & The SOLVD Investigators 1993, "Assessment of quality of life as observed from the baseline data of the Studies of Left Ventricular Dysfunction (SOLVD) trial quality-of-life substudy", *The American Journal of Cardiology,* vol. 71, no. 12, pp. 1069-1073.

Gott, M., Barnes, S., Parker, C., Payne, S., Seamark, D., Gariballa, S. & Small, N. 2006, "Predictors of the quality of life of older people with heart failure recruited from primary care", *Age and Ageing,* vol. 35, no. 2, pp. 172-177.

Gott, M., Barnes, S., Parker, C., Payne, S., Seamark, D., Gariballa, S. & Small, N. 2007, "Dying trajectories in heart failure", *Palliative medicine,* vol. 21, no. 2, pp. 95-99.

Hanratty, B., Hibbert, D., Mair, F., May, C., Ward, C., Capewell, S., Litva, A. & Corcoran, G. 2002, "Doctors' perceptions of palliative care for heart failure: focus group study", *British Medical Journal,* vol. 325, pp. 581-585.

Heiat, A., Gross, C.P. & Krumholz, H.M. 2002, "Representation of the Elderly, Women, and Minorities in Heart Failure Clinical Trials", *Archives of Internal Medicine,* vol. 162, no. 15, pp. 1682-1688.

Heo, S., Moser, D.K., Riegel, B. & Hall, L.A. 2005, "Testing the Psychometric Properties of the Minnesota Living with Heart Failure Questionnaire", *Nursing Research,* vol. 54, no. 4, pp. 265-272.

Heo, S., Lennie, T.A., Okoli, C. & Moser, D.K. 2009, "Quality of life in patients with heart failure: Ask the patients", *Heart & Lung: The Journal of Acute and Critical Care,* vol. 38, no. 2, pp. 100-108.

Hinton, J.M. 1963, "The physical and mental stress of dying.", *QJM,* vol. 32, pp. 1-21.

Ho, K.K., Anderson, K.M., Kannel, W.B., Grossman, W. & Levy, D. 1993a, "Survival after the onset of congestive heart failure in Framingham Heart Study subjects", *Circulation,* vol. 88, no. 1, pp. 107-115.

Ho, K.K., Pinsky, J.L., Kannel, W.B. & Levy, D. 1993b, "The epidemiology of heart failure: the Framingham study.", *J.Am.Coll.Cardiol.,* vol. 22, pp. 6-13a.

Hobbs, F.D.R., Kenkre, J.E., Roalfe, A.K., Davis, R.C., Hare, R. & Davies, M.K. 2002, "Impact of heart failure and left ventricular systolic dysfunction on quality of life: A cross-sectional study comparing common chronic cardiac and medical disorders and a representative adult population", *European Heart Journal,* vol. 23, pp. 1867-1876.

Jenkinson, C., Layte, R. & Jenkinson, D. 1997, "Development and testing of the UK SF-12.", *Health Service Research,* vol. 2, no. 1, pp. 14-18.

Juenger, J., Schellberg, D., Kraemer, S., Haunstetter, A., Zugck, C., Herzog, W. & Haass, M. 2002, "Health related quality of life in patients with congestive

heart failure: comparison with other chronic diseases and relation to functional variables", *Heart,* vol. 87, no. 3, pp. 235-241.

Karlsson, M.R., Edner, M., Billing, E. & Henriksson, P. 2008, "Patient-based vs. nurse-based NYHA classification of patients with chronic heart failure — Influence of mood", *European Journal of Cardiovascular Nursing,* vol. 7, no. Supplement 1, pp. S17-S17.

Krumholz, H.M. 1998, "Time to focus on the more typical heart-failure patients", *The Lancet,* vol. 352, no. 9121, pp. 3-4.

Lainscak, M. & Keber, I. 2003, "Patient's view of heart failure: from the understanding to the quality of life", *European Journal of Cardiovascular Nursing,* vol. 2, no. 4, pp. 275-281.

Levy, D., Kenchaiah, S., Larson, M.G., Benjamin, E.J., Kupka, M.J., Ho, K.K.L., Murabito, J.M. & Vasan, R.S. 2002, "Long-Term Trends in the Incidence of and Survival with Heart Failure", *The New England journal of medicine,* vol. 347, no. 18, pp. 1397-1402.

Lunney, J.R., Lynn, J., Foley, D.J., Lipson, S. & Guralnik, J.M. 2003, "Patterns of Functional Decline at the End of Life", *JAMA: The Journal of the American Medical Association,* vol. 289, no. 18, pp. 2387-2392.

Maisel, A.S., Krishnaswamy, P., Nowak, R.M., McCord, J., Hollander, J.E. & Duc, P. 2002, "Rapid measurement of B-type natriuretic peptide in the emergency diagnosis of heart failure", *New England Journal of Medicine,* vol. 347, pp. 161-167.

Mant, D., Hobbs, F.R. & Glasziou, P. 2008, "Identification and guided treatment of ventricular dysfunction in general practice using blood B-type natriuretic peptide.", *British Journal of General Practice,* vol. 58, no. 551, pp. 393-399.

Martensson, J., Stromberg, A., Dahlstrom, U., Karlsson, J.-. & Fridlund, B. 2005, "Patients with heart failure in primary health care: effects of a nurse-led intervention on health-related quality of life and depression", *European Journal of Heart Failure,* vol. 7, no. 3, pp. 393-403.

Masoudi, F.A., Havranek, E.P., Wolfe, P., Gross, C.P., Rathore, S.S., Steiner, J.F., Ordin, D.L. & Krumholz, H.M. 2003, "Most hospitalized older persons do not meet the enrollment criteria for clinical trials in heart failure", *American Heart Journal,* vol. 146, no. 2, pp. 250-257.

Masoudi, F.A., Rumsfeld, J.S., Havranek, E.P., House, J.A., Peterson, E.D., Krumholz, H.M. & Spertus, J.A. 2004, "Age, functional capacity, and health-

related quality of life in patients with heart failure", *Journal of cardiac failure,* vol. 10, no. 5, pp. 368-373.

McCarthy, M., Lay, M. & Addington-Hall, J. 1996, "Dying from heart disease", *Journal of the Royal College of Physicians of London,* vol. 30, no. 4, pp. 325-328.

Murberg, T.A., Bru, E., Svebank, S., Tveteras, R. & Aarsland, T. 1999, "Depressed mood and subjective symptoms as predictors of mortality in patients with congestive heart failure: a 2-year follow-up study.", *International Journal of Psychiatry in Medicine,* vol. 29, pp. 311-326.

Murray, S.A., Boyd, K., Kendall, M., Worth, A., Benton, T.F. & Clausen, H. 2002, "Dying of lung cancer or cardiac failure: prospective qualitative interview study of patients and their carers in the community", *British Medical Journal,* vol. 325, no. 7370, pp. 929.

National Institute for Health and Clinical Excellence 2003, *Management of chronic heart failure in adults in primary and secondary care.*

Ni, H., Toy, W., Burgess, D., Wise, K., Nauman, D.J., Crispell, K. & Hershberger, M.D. 2000, "Comparative Responsiveness of Short-Form 12 and Minnesota Living with Heart Failure Questionnaire in patients with heart failure", *Journal of Cardiac Failure,* vol. 6, pp. 83-91.

Nordgren, L. & Sörensen, S. 2003, "Symptoms experienced in the last six months of life in patients with end-stage heart failure", *European Journal of Cardiovascular Nursing,* vol. 2, no. 3, pp. 213-217.

Northern Ireland Statistics and Research Agency 2008, , *Northern Ireland Multiple Deprivation Measure 2005.* Available: http://www.nisra.gov.uk/aboutus/default.asp2.htm [2008, November] .

Rector, T.S. 2005, "A Conceptual Model of Quality of Life in Relation to Heart Failure", *Journal of cardiac failure,* vol. 11, no. 3, pp. 173-176.

Rector, T.S., Anand, I.S. & Cohn, J.N. 2006, "Relationships Between Clinical Assessments and Patients' Perceptions of the Effects of Heart Failure on Their Quality of Life", *Journal of cardiac failure,* vol. 12, no. 2, pp. 87-92.

Rector, T.S. & Cohn, J.N. 1992, "Assessment of patient outcome with the Minnesota Living with Heart Failure questionnaire: Reliability and validity during a randomized, double-blind, placebo-controlled trial of pimobendan", *American Heart Journal,* vol. 124, no. 4, pp. 1017-1025.

Rector, T.S., Kubo, S.H. & Cohn, J.N. 1987, "Patient's self assessment of their congestive heart failure: content reliability, and validity of new measure: the Minnesota Living with Heart Failure Questionnaire.", *Heart Failure,* vol. 3, pp. 198-219.

Rich, M.W., Beckham, V., Wittenberg, C., Leven, C.L., Freedland, K.E. & Carney, R.M. 1995, "A Multidisciplinary Intervention to Prevent the Readmission of Elderly Patients with Congestive Heart Failure", *The New England journal of medicine,* vol. 333, no. 18, pp. 1190-1195.

Rogers, A.E., Addington-Hall, J.M., Abery, A.J., McCoy, A.S., Bulpitt, C., Coats, A.J. & Gibbs, J.S. 2000, "Knowledge and communication difficulties for patients with chronic heart failure: qualitative study", *BMJ (Clinical research ed.),* vol. 321, no. 7261, pp. 605-607.

Rohrbaugh, M.J., Shoham, V. & Coyne, J.C. 2006, "Effect of Marital Quality on Eight-Year Survival of Patients With Heart Failure", *The American Journal of Cardiology,* vol. 98, no. 8, pp. 1069-1072.

Saunders, W.B. (ed) 2000, *Dorlands Illustrated Medical Dictionary*, 29th edn, Harcourt Health Sciences Company, Philadelphia.

Scherer, M., Himmel, W., Stanske, B., Scherer, F., Koschack, J., Kochen, M.M. & Herrman-Lingen, C. 2007, "Psychological distress in primary care patients with heart failure: a longitudinal study", *British Journal of General Practice,* vol. 57, pp. 801-807.

Smith, L.E., Fabbri, S.A., Pai, R. & et al 1997, "Symptomatic improvement and reduced hospitalisation for patients attending a cardiomyopathy clinic", *Clinical Cardiology,* vol. 20, no. 11, pp. 949-954.

Smith, W.C., Crombie, I.K., Campion, P.D. & Knox, J.D. 1985, "Comparison of response rates to a postal questionnaire from a general practice and a ressearch unit.", *British Medical Journal,* vol. 291, no. 6507, pp. 1483-1485.

Sparrow, N., Adlam, D., Cowley, A. & Hampton, J.R. 2003, "The diagnosis of heart failure in general practice: implications for the UK National Service Framework", *European Journal of Heart Failure,* vol. 5, no. 3, pp. 349-354.

Stewart, A.L., Greenfield, S., Hays, R.D., Wells, K., Rogers, W.H., Berry, S.D., McGlynn, E.A. & Ware, J.E.,Jr 1989, "Functional status and well-being of patients with chronic conditions. Results from the Medical Outcomes Study", *JAMA : the journal of the American Medical Association,* vol. 262, no. 7, pp. 907-913.

Stewart, S., MacIntyre, K., Hole, D.J., Capewell, S. & McMurray, J.J. 2001, "More 'malignant' than cancer? Five-year survival following a first admission for heart failure", *European journal of heart failure : journal of the Working Group on Heart Failure of the European Society of Cardiology,* vol. 3, no. 3, pp. 315-322.

Stomberg, A. & Martensson, J. 2003, "Gender differences in patients with heart failure", *European Journal of Cardiovascular Nursing,* vol. 2, pp. 7-18.

Taylor, J. & Stott, D.J. 2002, "Chronic heart failure and cognitive impairment: co-existence of conditions or true associations?", *Eur.J.Heart Fail.,* vol. 4, pp. 7-9.

Testa, M.A. & Simonson, D.C. 1996, "Assessment of Quality-of-Life Outcomes", *The New England journal of medicine,* vol. 334, no. 13, pp. 835-840.

The CONSENSUS Trial Study Group 1986, "Effects of enalapril on mortality in severe congestive heart failure of the cooperative north Scandinavian enalapril survival study (CONSENSUS)", *New England Journal of Medicine,* vol. 314, pp. 1547-1552.

The Study of Left Ventricular Dysfunction (SOLVD) Investigators 1996, "Baseline quality of life as a predictor of mortality and hospitalisation in 5,025 patient with congestive heart failure", *American Journal of Cardiology,* vol. 78, pp. 890-895.

The Study of Left Ventricular Dysfunction (SOLVD) Investigators 1991, "Effect of enalapril on survival in patients with reduced left ventricular ejection feaction and congestive heart failure", *New England Journal of Medicine,* vol. 325, pp. 293-302.

Thomas, K. 2000, *The Gold Standards Framework.* Available: http://www.goldstandardsframework.nhs.uk/non_cancer.php [2008, January] .

Uretsky, B.F. & Sheahan, R.G. 1997, "Primary prevention of sudden cardiac death in heart failure: will the solution be shocking?", *Journal of the American College of Cardiology,* vol. 30, no. 7, pp. 1589-1597.

Vogels, R.L., Oosteman, J.M., van Harten, B., Scheltens, P., van der Flier, W.M., Schroeder-Tanka, J.M. & Weinstein, H.C. 2007, "Profile of cognitive impairment in chronic heart failure", *Journal of American Geriatrics Society,* vol. 55, no. 11, pp. 1764-1770.

Ward, C. 2002, "The need for palliative care in the management of heart failure", *Heart,* vol. 87, no. 3, pp. 294-298.

Wensing, M., Smits, A. & Van Montfort, P. 1996, "Evaluation of general practice care by chronically ill patients: the effect of the method of administration.", *Family Practice,* vol. 13, no. 4, pp. 386-391.

Wilems, D.L., Hak, A., Visser, F.C., Cornel, J. & Van der Wal, G. 2006, "Patient work in end-stage heart failure: a prospective longitudinal multiple case study", vol. 20, pp. 25-33.

World Health Organisation 2007, "Palliative care. Cancer control:knowledge into action" in
WHO guide for effective programmes WHO Press, Geneva.

Zigmond, A.S. & Snaith, R.P. 1983, "The Hospital Anxiety and Depression Scale", *Acta Psychiatrica Scandinavica,* vol. 67, pp. 361-370.